IN THE DISTRICT COURT OF THE UNITED STATES
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE:
NATIONAL PRESCRIPTION OPIATE LITIGATION

CASE TRACK THREE

Case No. 1:17-md-2804
Cleveland, Ohio

October 6, 2021
8:54 A.M.

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VOLUME 3

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TRANSCRIPT OF JURY TRIAL PROCEEDINGS,

BEFORE THE HONORABLE DAN A. POLSTER,

UNITED STATES DISTRICT JUDGE,

AND A JURY.

- - - - -

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Special Master David Cohen

- - - - -

WEDNESDAY, OCTOBER 6, 2021, 8:54 A.M.

THE COURT: Okay. Everyone can be seated.

The plaintiffs wanted to address something?

MR. LANIER: Yes, Your Honor. Thank you for your kindness in giving us a couple of minutes this morning.

With respect, Your Honor, your rulings and process for conducting this trial have unduly prejudiced the right and ability of the plaintiffs to present their case by not allowing fair questions to the witness yesterday.

Here is the impossible predicament you leave the plaintiffs in.

One, plaintiffs have the burden of proof.

Two, defendants, in their unlimited-in-time opening statement, were incessant in arguing that the plaintiffs must show diversion on a store level in the counties.

Three, plaintiff has that, what's been made critical proof in this case before the jury, but no way to show it under your rules of court.

Four, to wit: The defendant stores fulfilled the verdant prescriptions that the pharmacists knew or reasonably should have known were illegal, specifically with Dr. Veres and Dr. Torres in these

stores, in these counties.

This is shown in documents. These documents are properly authenticated. They are properly admissible evidence in a civil case.

08:56:42 They can and should be admitted, read to a jury, and used as a basis for cross-examining a witness.

The witness yesterday was Mr. Tom Davis, the Vice President and head of CVS's division that oversees pharmacy actions regarding diversion and policy.

08:57:01 He is a proper person to ask questions of regarding such documents and issues, even if he doesn't remember or hasn't seen the document.

To not allow such documents to be read to the jury, probed with the witness, and tested as to their

08:57:21 content and policies comparing it with the witness' testimony is unfair, it's wrong under the law, and it's highly prejudicial.

For example, CVS stores filled prescriptions written by Dr. Veres for seven years after

08:57:40 he first came on to CVS's radar screen as an overprovider.

There were reports of Dr. Veres being an overprovider, of Dr. Veres refusing interviews, of Dr. Veres finally giving an interview in which he said he

08:57:57 had a host of patients --

THE COURT: Hold it. Hold it. Hold it.

Mr. Lanier, you're saying all this. None of this is in evidence.

All right? None of this is in evidence.

08:58:09 It may come in with someone else. You could have asked this witness if he knew anything about any -- if this happened, I don't know, was this after 2012 when he took his position?

MR. LANIER: Your Honor, yes. That's what

08:58:24 the documents --

THE COURT: Well, then, you could have asked him -- you know, I allowed you to ask him about Dr. Torres, Dr. Veres, if he knew anything about it.

MR. LANIER: These were the documents, Your

08:58:37 Honor --

THE COURT: If these were documents -- Mr. Lanier, the only thing I didn't allow you to do is just do wholesale reading of the contents of the document that the witness said he didn't -- he never saw and knew

08:58:48 nothing about, but you could have asked him, if this happened in his division, in his office, people under his control and he knew nothing about it, you could have -- you could have kept going at it and say, "Why didn't you?"

MR. LANIER: Your Honor --

08:59:02

THE COURT: -- this is in your, you know -- but and I would have allowed you to ask him that question.

MR. LANIER: Your Honor --

08:59:05 THE COURT: This happened under your division, you knew nothing about it; why not.

So I don't -- my recollection is the only thing I didn't allow you to do is just do wholesale reading of a document with no real question.

08:59:20 MR. LANIER: Your Honor, I believe the record will reflect --

THE COURT: All right. Well --

MR. LANIER: -- very differently and I would like to finish, if I could, putting on the record

08:59:27 what I believe.

THE COURT: And again, if you thought, if you thought -- the time to do this was requesting a side-bar at the time. All right?

If you think that my rulings are wrong,

08:59:38 unfair, or I have a different strike zone for one side or the other, it's appropriate to raise that contemporaneously while the witness is there.

But, I mean, to go back now, I think -- I think my rulings were correct.

08:59:53 MR. LANIER: Hey, Your Honor, if I could

finish making my record. If you'd like me to make it in writing, I'm glad to.

THE COURT: Okay.

MR. LANIER: Your Honor, you would not let me ask this question, questions of this witness, if he was not on the document or did not recall the document, and for me to be able to put this case --

THE COURT: Hold on. What questions?

I mean --

MR. LANIER: The questions --

THE COURT: To be candid, this isn't making a record. Okay?

You're complaining in total about things I did over a course of four hours, all right?

So you can -- I'll let you finish and then we'll move on because it's not worth anything, in my view.

MR. LANIER: Okay. In that regard, Your Honor, for me to have been able to use with this witness Plaintiffs' Exhibit 8496, I would need to have Rachel Joseph on the stand to testify about the document.

THE COURT: Someone give me 8496 so I can look at it. What --

By the way, I let you use any exhibit you introduced. All right? I let you start, start

questioning.

MR. LANIER: With due respect, Your Honor, if the witness was not on the exhibit or did not remember it, you insisted that I move on and it wasn't appropriate questioning for the witness.

09:01:01

THE COURT: Well, no. No. I didn't let you just keep reading and reading.

Getting the whole contents in sort of through the back door.

09:01:11

If there was a question, if the document was written by his underling, his direct report, you could have asked him, "Well, why didn't you get it?"

MR. LANIER: I tried to do that, Your Honor, and I was shut down on that.

09:01:25

THE COURT: I don't believe so. I don't think the record reflects that.

I would allow these questions.

There were a whole lot of questions I thought you were going to ask which you didn't.

09:01:33

MR. LANIER: And in that regard, Your Honor, I will go forward to continue to say if the document is admissible into evidence, it is appropriate for a document to be read.

THE COURT: I don't know if it's admissible into evidence or not.

09:01:42

I mean, if the defendants haven't objected and you just move them in wholesale at the beginning of the case, fine. And they don't object, fine, then it's in.

09:01:53 But I don't know -- you know, I --

MR. LANIER: These documents, Your Honor, we contend are properly admissible. They include Plaintiffs' Exhibit 8500, 23365.

THE COURT: All right.

09:02:07 MR. LANIER: 8494.

THE COURT: Mr. Lanier, I've admitted -- I have admitted every document that you offered yesterday.

MR. LANIER: Your Honor, we would agree.

THE COURT: I did not exclude a single

09:02:21 document that you offered into evidence, and I admitted several over the defendants' objection.

The record's clear on that.

MR. LANIER: Your Honor, we further contend that not only should these documents be admitted into

09:02:33 evidence, but that they should be able to be read to the jury. Otherwise, the jury has no basis for assimilating that evidence, and they should serve as a basis to examine a witness whose job it is to see that these things don't happen.

09:02:47 If the witness then wants to say, "I don't

remember that," so be it. If the witness then wants to say, "I don't know about that," so be it. If the witness then wants to say, "That happens in our stores and that is fine CVS behavior," so be it. But the witness must be allowed to testify about it.

09:03:05

The Court's rulings and decisions on how trial and cross-examination must proceed make a proper presentation of this evidence impossible. Under the Court's procedures, we've got to put on the CVS witness who actually noticed, first noticed the problem with Dr. Veres, then the next CVS witness who documented the problem, and then the next and then the next, until we finally present the witness who interviewed Dr. Veres. A parade of five, ten witnesses is impossible in a case where we're limited in the deposition numbers we were allowed, we were limited in subpoena power, and we're limited in our time for trial.

09:03:20

09:03:37

Furthermore, by not allowing the reading of properly admissible documents and proper demonstratives like the *Holiday* case to inform the jury and then ask questions is also unfair and unduly prejudices the plaintiffs.

09:03:55

THE COURT: I allowed all the questions you asked. You asked him about *Holiday*.

MR. LANIER: And you told me to move on and

09:04:08

I wasn't allowed to read any more out of the case.

I would also like to address the fallout. Plaintiffs expected to have Mr. Davis on the stand for two days. Our witnesses were ordered accordingly. They are coming in from out of town.

09:04:26

By shutting down 80 to 90 percent of our examination --

THE COURT: Wait.

You expected a long direct examination by CVS. There was one question, all right?

09:04:33

MR. LANIER: I -- I also expected to go myself with him well into today, as I said on the record.

It left the plaintiffs scrambling to bring in witnesses leaving inadequate time to get them here, get adjusted to time zones, and prepared to take the stand and efficiently present their testimony.

09:04:48

In a timed trial, this is a grievous consequence. At some point, I will need to make a bill with the testimony that the Court not allowed me to secure with Mr. Davis and other witnesses should it happen again in the future. I can do that should the Court allow it by narrative, or by Q & A, but I would ask that time not be docked against my clock and it will take a block of time.

09:05:03

09:05:16

I would also ask if the Court insists on

these rules, that I be allowed under Rule 43 to compel attendance of the many, many witnesses that will be needed to cover each individual document of each defendant, and I would ask the Court to drop the time
09:05:32 requirements and allow the nine to twelve months it may take to try this case in that event.

THE COURT: Obviously all that's rejected, Mr. Lanier, and you know that.

MR. LANIER: And I understand that, Your
09:05:46 Honor, and I'm making my --

THE COURT: Look, as I said, you can put anything on the record now. It's untimely and ineffective and candidly of no value for you to say it now.

09:05:56 The time to have raised some of this would have been contemporaneously if you felt that my rulings were incorrect or unfair, all right? I might have reconsidered something.

Maybe I didn't understand where you were
09:06:07 going. I mean, I was a trial lawyer and if I thought the Judge didn't understand where I was going, I asked for a side-bar and I said, "Judge, I'd like to make a proffer. This is what -- the questions I want to ask, this is what I expect to elicit, this is what I think is relevant."

09:06:25 I mean, everyone knows how to do that.

Your raising this now doesn't help anyone. All right?

MR. LANIER: Thank you, Your Honor.

THE COURT: Again, you can't -- you're suggesting that I just let you, like, get up and read in a whole lot of facts and ask the witnesses is this true.

I mean, look, you could have -- you can't -- you can't put in through your testimony or through your questions a whole lot of facts that the witness knows nothing about.

Everyone knows that. Okay? Then -- because I've already instructed the jury to disregard your questions.

It's only the answers of the witness. You can ask whatever questions you want of him. I mean, I think you made some good points that, candidly, this guy knew a lot less than he should have known, given his position.

I think that's one of the things you were trying to show. I think you showed that. He should have known a lot more than he did. He should have been a lot more curious, in my opinion, as to what was, you know, what was going on in the company.

He wasn't. Okay. You made that point.

But, all right, the --

MR. LANIER: The rest of our concerns Mr. Weinberger will address.

MR. WEINBERGER: Your Honor, about a month ago, we had a hearing before Special Master Cohen that you ordered or agreed with so that we could provide a sampling of documents and get some sense of what were the guardrails surrounding the admissibility and use of those documents at trial.

09:07:41

It's relevant to what happened yesterday because what we -- what the rulings reflected was the fact that we didn't need, in effect, a sponsoring witness for documents that were clearly within the control and custody of the defendants, had been produced by the defendants, and so long as yesterday we were asking the questions surrounding a document of somebody who was in the department or in the division that oversaw the conduct that was reflected in those documents, that if the documents came from the defendants, the fact that the witness's name was not on those documents would not prevent us from cross-examining the witness on those issues.

09:08:01

09:08:26

09:08:48

That's what we were trying to do yesterday. And I appreciate the fact, Your Honor, that perhaps there were some additional questions that could have been asked. However, what Mr. Lanier was attempting to do was

09:09:02

to show the document and -- to the witness, even though he wasn't a recipient of the document, but we established that it was within his department, and to ask him about statements that were made specifically on this Veres issue which is a critical issue to the case.

09:09:25

THE COURT: Well, I allowed -- I allowed you to ask him questions about Dr. Veres and Dr. Torres.

All right. Look, as I said, I allowed questions on every document.

09:09:39

What I just didn't allow was wholesale reading with no real question because you were getting in something he knew nothing about.

MR. WEINBERGER: Well, the point was --

THE COURT: And if you wanted to establish,

09:09:52

look, I know nothing about Torres, I know nothing about Veres, you had established that and that's your point. All right. He knows nothing about it and he should.

MR. WEINBERGER: But we should be able to use the document to impeach the witness and to --

09:10:05

THE COURT: Impeach him about what?

MR. WEINBERGER: So if there was a statement made about some -- something that their division, their regulatory affairs division learned about Veres, we should have had the ability to read the

09:10:21

statement, which is what Mr. Lanier was doing, and ask

him, A, did he hear about it; B, would that have been important to your division; C, what --

THE COURT: I didn't hear -- I didn't hear any questions like that.

09:10:36 I didn't hear any questions like that.

MR. LANIER: Because I was not allowed to do that, Your Honor. That's the whole point.

THE COURT: I disagree.

MR. LANIER: The document --

09:10:43 THE COURT: I disagree, all right. I don't think that's what happened so.

MR. LANIER: If the document is evidence, I should be allowed to read the evidence to the jury.

THE COURT: I didn't know it's evidence. I

09:10:52 didn't know it's evidence. You hadn't -- I mean if you had had -- if all these things were admitted beforehand, that should have been presented to me. All right? Then they don't even have to be offered. They all should come in by stipulation if there's -- if there's documents that

09:11:06 you've, that both sides have agreed are admitted by stipulation, fine, they should come in. We don't need to waste time at the end of every day offering them and having rulings.

I mean I don't know any of this. I mean to

09:11:23 my knowledge, no documents have been stipulated to as

admissible.

MR. WEINBERGER: Your Honor --

THE COURT: You know, there's no disagreement on authenticity, but there's -- so, look, again, respectfully, saying this now doesn't help me and it doesn't help you.

So the time to make an objection is contemporaneous.

MR. WEINBERGER: Your Honor, if I --

THE COURT: Let me finish my statement. All right. You can make your record.

MR. WEINBERGER: May I suggest this, Your Honor?

Over the course of the afternoon, I think you can appreciate the fact that as we got these rulings one after another that limited our ability to do what we intended to do with this witness, that set up parameters that we understood was going to be the way that you were going to rule on future issues associated with other things that we wanted to get into evidence with respect to this witness.

This, you know, it all came as a surprise to us in light of what --

THE COURT: I don't understand. What is the surprise? I don't --

MR. WEINBERGER: Because we had a hearing before Special Master Cohen a month ago, and he not only made some rulings, but indicated clearly what -- how it was that you were going to handle these corporate documents and what would or would not be required in order for us to be able to use them.

09:12:46

So here's my -- here's my request and my potential solution. We would like the ability to recall Mr. Davis to go through and make our record and ask questions and --

09:13:07

THE COURT: If you want to use your time recalling him, fine. You can recall him.

MR. DELINSKY: Your Honor --

THE COURT: They can recall him. If they -- I mean, I'm not going to let -- but it's maybe very short. I mean, not just for me to make -- I mean if you -- well --

09:13:16

MR. DELINSKY: Your Honor --

THE COURT: All right. Let's move on. All right? Let's move on.

09:13:28

Again this is not helpful to me, it's not helpful to you.

All right. If both sides can agree on documents that are admissible, just put them in by stipulation. You've had months and months to do that.

09:13:38

All right.

MR. DELINSKY: Your Honor, can we leave this -- I'm just not hearing there's an order saying they can recall him because that would be very prejudicial to Mr. Davis.

09:13:52

THE COURT: Oh, I don't think it's prejudicial at all.

If they want to take their hours, I'm not going to let them go -- well --

09:13:59

MR. DELINSKY: Well, Your Honor, we'd like the opportunity for --

THE COURT: Hold it.

I'm only going to allow him to be recalled if you can convince me there was something you should be

09:14:11

able to do and my rulings were erroneous, I'll let you go into that but you haven't done that.

So if you can, you know, write some brief and convince me -- but you'll have to show that you asked that and I wouldn't let it be asked; not that I just

09:14:26

stopped or, you know, the only thing I stopped you from doing, Mr. Lanier, is just wholesale reading of documents and there was no real question.

I would have asked you, you know, you want to say -- all right, see this statement, sir? Do you

09:14:40

agree with it, do you disagree with it? Is this CVS

policy or not?

Those are all proper. There were a whole lot of things that you didn't go into that I would have let you go into with him.

09:14:52 You chose not to.

MR. LANIER: We will file a brief on this, Your Honor, and we will page and line the rulings and the instructions that I was given with the questions I would have asked.

09:15:01 THE COURT: And from now on, if either side thinks that my evidentiary rulings are incorrect, everyone knows you've got to make a contemporaneous objection and give the Court the opportunity to reconsider it.

09:15:15 Doing it after the witness is off doesn't accomplish a thing.

All right. At this point. It's already 9:15. From now on -- are there still issues with documents or have those been worked out?

09:15:31 Objections to documents with this next witness?

MR. HYNES: Your Honor.

THE COURT: I'm going to charge both sides any time I spend now on these documents but I'll deal

09:15:41 with them.

What are the -- are there any objections? And I don't even have the documents so if there are, let me have them and I'll rule.

MR. HYNES: Your Honor, Paul Hynes for CVS. Yes, there are still some outstanding issues.

THE COURT: All right. From now on, this time is being charged against both parties so let me have -- hand me up the documents and give them to me. I don't have them. I've got a bunch of e-mails that are again of no value, I couldn't do any preparation, so --

MR. HYNES: Your Honor, we handed up just some exemplar documents because the documents we're discussing now fall into the same bucket.

THE COURT: All right. These are documents that the plaintiffs are seeking to use with Ms. Lembke?

MR. HYNES: Correct.

MR. WEINBERGER: Do you have a copy of the exemplar documents?

THE COURT: So the first one I've got is 8663. All right.

All right. I mean, I've got a bunch of documents here. 8663, 8664, 8586. Those are the three that have been handed to me.

What --

MR. HYNES: Correct.

THE COURT: What is the objection?

MR. HYNES: The objection, first, Your Honor, is that plaintiffs cannot admit these documents through an expert witness. An expert witness cannot be used as a conduit to admit evidence into the record that's otherwise inadmissible.

These documents, many of them are very old, from 20 years ago. None of the witnesses who are on these documents are on plaintiffs' witness list. None have been deposed. None will testify at trial.

THE COURT: Well, hold it.

Were these documents that Ms. Lembke, that was shown to Ms. Lembke in preparation of her report and that she reviewed and she's commented and opined on?

MR. WEINBERGER: Yes. Yes, Your Honor.

THE COURT: All right. Then they come in.

I mean, and they are CVS documents, all right. She got them. She reviewed them.

MR. HYNES: Your Honor, they are Purdue documents. They were not produced by CVS. We have not located these records in CVS documents.

THE COURT: It says CVS. The document I'm looking at says CVS Pharmacy 8663.

MR. HYNES: Plaintiffs cannot use an expert witness as a conduit to admit documents.

They need a witness with knowledge of the documents to admit them into evidence.

MR. WEINBERGER: Your Honor, we have --

THE COURT: No, I disagree.

09:18:19 I mean, Ms. Lembke can testify that based on whatever she was given, okay.

If you can point out that what she was given was untrue or inaccurate, you can certainly cross-examine her on that. All right?

09:18:34 At least they are CVS records, okay? 8663 is a CVS record. I don't know what 8664 is.

MR. HYNES: Just to clarify, Your Honor --

THE COURT: CVS, okay.

MR. HYNES: We're not saying they can't be

09:18:48 used with Ms. Lembke today. We're saying they can't be admitted into evidence through Ms. Lembke. I just want to make sure I'm being clear with Your Honor.

We're not objecting to them being used but they can't be admitted into evidence, and if they are

09:19:02 used there should be a limiting instruction that they are not being admitted into evidence.

MR. WEINBERGER: Your Honor, at least one of these documents was the subject of our hearing with Special Master Cohen about a month ago.

09:19:16 We provided a certification from Purdue

that these documents were business records of Purdue.

THE COURT: Well --

MR. WEINBERGER: Pursuant to the rules.

MR. HYNES: But we objected to that certification a few days after the hearing, we objected in writing.

A certification is not proper. It's executed by an outside lawyer for Purdue who has no personal knowledge of the documents.

09:19:39 THE COURT: Which Purdue document are we talking about? What's a Purdue document, 8586? I mean --

MR. HYNES: Your Honor, any of these documents were produced by Purdue. None of them were

09:19:49 produced by CVS.

THE COURT: I don't care who produced them.

If they are CVS documents, they should presumptively come in.

If they're Purdue documents, I mean,

09:19:59 documents generated by Purdue, I don't see how they can come in through Ms. Lembke. All right? They can say she reviewed them, all right, and she can testify that she reviewed them, and you can cross-examine on it.

MR. HYNES: And we're okay with that.

09:20:14 THE COURT: But I don't think you can admit

a Purdue document through Ms. Lembke. All right? She doesn't know if it's -- anything about it. You've shown it to her so she can say she looked at it and --

MR. WEINBERGER: We're not attempting to admit the documents through Dr. Lembke.

THE COURT: Okay.

MR. WEINBERGER: On a separate issue, we have a certification.

THE COURT: All right, fine. The point, she can testify -- if she looked at them and it helped form her opinion, she can -- she can say, "I looked at this and I looked at that and I've reviewed all this and, you know, these are my conclusions."

MR. HYNES: We would submit we're fine with using them and not admitting them today. The certification seems like a different issue we can address at some other point in time. We object to it --

THE COURT: Let's move on.

MR. HYNES: And just to be clear, those are exemplar documents. There were other documents Purdue produced that fall into this bucket. We didn't want to burden you.

THE COURT: They are not trying to admit Purdue documents through Lembke, all right? If she's reviewed them, she can -- she's an expert. She can

testify about anything she was shown, and if you want to say what she was shown was inaccurate, you can certainly cross-examine her on that or bring that out and undermine her opinion that way.

09:21:30 That's fine.

All right. Was there any -- I was told there were a bunch of other objections.

Have those been worked out?

MS. FUMERTON: Your Honor, this is Tara

09:21:44 Fumerton on behalf of Walmart.

Plaintiffs did withdrew a number of them but I have a clarifying question for plaintiffs based on Mr. Weinberger's representation.

So are plaintiffs not attempting to admit

09:21:55 any of these documents through Ms. Lembke? They are simply going to ask her about them?

MR. WEINBERGER: No, we are not seeking to admit them through this witness.

But clearly she's going to opine that she

09:22:06 relied on these documents, and the admissibility of those documents will come -- will be handled through other means.

THE COURT: Right. If they're going to offer them, then we'll have to address them at that time

09:22:18 but anyone knows an expert can, you know, anything that

an expert saw or reviewed, both sides can examine on and cross her on that.

MS. FUMERTON: Your Honor, with that clarification, then we are going to reserve our objections to these documents if and when plaintiffs try to admit them.

09:22:31

THE COURT: All right. Okay.

Was there anything else dealing with Lembke? There was an e-mail I got which had several other categories.

09:22:40

Have those been taken care of?

MR. WEINBERGER: Yes, Your Honor.

We have had -- it had to do with our demonstratives and I think we've taken Special Master Cohen's rulings and altered the demonstratives appropriately.

09:22:53

THE COURT: All right. Well, there was some other -- all right. That's -- I thought there was a lot --

MR. HYNES: Your Honor, the first bullet of our e-mail, those documents were withdrawn so I think we're in good shape now.

09:23:08

THE COURT: All right. Purdue, and then Walmart is objecting to settlements.

There were a couple -- I mean Walmart's

09:23:17

objections are noted but if there were settlements within, within this time period on the subject of this case like I admitted them for CVS, they would come in.

MS. FUMERTON: Yes, Your Honor, we understand your prior rulings on this.

09:23:32

This particular document plaintiffs actually withdrew this morning so I don't think this issue is ripe yet.

THE COURT: Okay. All right. Well, then, let's proceed with Dr. Lembke.

09:23:40

MR. DELINSKY: Your Honor?

THE COURT: Yes.

MR. DELINSKY: I just wanted a general reminder of that instruction we talked about last night.

09:23:55

THE COURT: Yes, I have that somewhere.

Okay. I will say that at the beginning.

MR. DELINSKY: Thank you, Your Honor.

(Jury in.)

THE COURT: Okay. Good morning, please be seated.

09:25:38

Ladies and gentlemen, again I apologize for the delay. We had some evidentiary matters that I needed to take up with the lawyers.

Before we begin with the next witness, yesterday Mr. Lanier asked some questions of Mr. Davis as

09:25:46

to whether he had done anything to prepare on his own for his testimony.

I allowed the questions, they are perfectly permissible questions, but I want you to understand that a witness has no obligation to do any preparation on his or her own for testimony. He or she can but is under no obligation to do so, and you're not to draw any negative inference if a witness is asked and said, "I didn't do anything."

09:26:21 All a witness is obligated to do is show up at a specified time, listen to both sides' questions and answer to the best of his or her ability.

Okay. Mr. Lanier, you may call your next witness.

09:26:36 MR. LANIER: Yes, Your Honor.

May it please the Court. Good morning, ladies and gentlemen. Your Honor, our next witness is Dr. Anna Lembke, L-E-M-B-K-E.

THE COURT: Good morning. Dr. Lembke, if

09:27:08 you could raise your right hand, please.

ANNA LEMBKE

of lawful age, a witness called by the PLAINTIFFS, being first duly sworn, was examined and testified as follows:

09:27:16 THE COURT: You may take off your mask while you're testifying.

DIRECT EXAMINATION OF ANNA LEMBKE

BY MR. LANIER:

Q. May it please the Court, ladies and gentlemen.

09:27:32 Dr. Lembke, I really can't see you without putting these on, so excuse me for a moment.

Would you please introduce yourself to the jury?

A. Sure.

09:27:45 So my name is Anna Lembke. I am a psychiatrist with expertise in addiction medicine, in chronic pain.

I am on the faculty at Stanford University School of Medicine, and my role there is three basic

09:28:06 parts.

I see patients, I teach medical students, residents, fellows and in the broader medical community.

Q. I'm going to interrupt you for a moment because I want to put this into a framework for us.

09:28:23 My goal is to ask you questions in four

different broad areas and the first one we're already starting on, and that is -- oh, Mr. Pitts, could we turn on the monitors, please?

Thank you. Thank you.

09:28:42 My goal is, this is your roadmap, is to ask you in four main areas. The first, about you as a person. And what I've got in that regard is your CV. And a few other things.

And I'll ask you about those, but first let 09:28:57 me just ask some basic questions.

Where do you live?

A. I live in California.

Q. And you got into Cleveland when?

A. Late last night.

09:29:08 Q. All right. And you and I met to discuss this morning over breakfast at what time?

A. 7:30.

Q. All right. Thank you for being here and coming on quick notice.

09:29:25 Do you treat people who are addicted to various things?

A. Yes.

Q. Do you write prescriptions?

A. Yes.

09:29:38 Q. Do you teach and train others to do the same?

A. Yes.
Q. Do you lecture about these things?
A. Yes.
Q. Do you routinely deal with pharmacists in conjunction with your patient care?
09:29:57
A. Yes.
Q. All right. Dr. Lembke, I've got a copy of your CV, which has been marked as demonstrative number 18, and so the jury understands a bit of this, and we'll be getting to purpose -- ah, we'll hold off.
09:30:16
This is -- you are Anna Lembke, M.D., fair?
A. Yes.
Q. What is the difference between a psychiatrist and a psychologist?
09:30:31
A. A psychiatrist goes to medical school and so has an M.D., and a psychologist is either trained through a Ph.D. program or a Psy.D program. Psychologists generally cannot prescribe medications.
Q. So are you a psychiatrist or a psychologist?
09:30:50
A. I am a psychiatrist.
Q. And that's the M.D., you're a medical doctor?
A. Yes. I have gone to medical school and I received medical training and residency and fellowship.
Q. All right. And if we look at your job title as
09:31:07
it's listed at least on your CV, tell the jury what it

means that you are a Professor of Psychiatry and Behavioral Sciences.

Let's start there.

A. I am on the faculty of Stanford University School of Medicine. I occupy the classic three-legged stool of academic medicine, which means that I see patients, I teach, and I do research.

Q. All right. So the three legs of your stool are teaching.

How often do you teach?

A. I teach every day. That's a major part of what I do.

I teach in classrooms at Stanford and nationally, and I also do what is called bedside teaching. I teach while seeing patients, together with medical students, residents and fellows.

Q. And then the second leg of your stool was treatment or what did you call it?

A. Scholarly work.

Q. Oh, scholarly work. And explain what you mean by scholarly work.

A. I -- my role is also as a researcher, so the scholarly work encompasses my research.

Q. And what's the third leg of your stool?

A. Clinical work.

Q. And clinical is a familiar term to many of our jurors, but what is clinical work?

A. Clinical work means that I actively see patients, I have seen patients my entire career, and about 70 percent of my job is seeing patients.

I'm a clinician. I'm a doctor who treats patients.

Q. All right. You also have a courtesy appointment in anesthesiology and pain medicine.

Can you explain what that is, please?

A. So I did have a courtesy appointment until this year when I was promoted to full Professor, but what that means is that I work closely with my colleagues in pain anesthesia to treat patients who are struggling with a variety of pain conditions.

Q. All right. And then all of this is done at Stanford University?

A. Yes.

Q. To do that, you've -- and the law requires me to put certain of your qualifications down on the record as well as informing the jury, but let's get that done fairly briefly.

Do you have an undergraduate degree?

A. Yes.

Q. Tell the jury about your undergraduate degree,

please, briefly.

A. I was a humanities major at Yale.

Q. All right. And then you graduated with a Bachelor's in '89, then you went to the University of Beijing?

09:34:14

A. Yes.

Q. What is -- what did you do there?

A. I continued my studies in Chinese and then I became a middle school teacher in Changsha, China, to students at Yali Middle School, which is an extension school of Yale University.

09:34:31

Q. So could you break out into Chinese for us here?

A. I could.

Q. The Court Reporter would love you.

Then from there, it looks like you got your medical degree.

09:34:43

Where did you get your medical degree?

A. At Stanford University.

Q. And you did a residency in pathology.

Can you explain what pathology is?

09:34:55

A. Pathology is the study of disease, and the pathologist has different roles, but the ones you might be most familiar with are examining bodies after death, during autopsy, or examining tissue samples, for example breast biopsies to determine the absence or presence of

09:35:17

cancer.

Q. In addition to that extended residency you did, you did a residency in internal medicine.

Can you explain what internal medicine is -- or, no, you did an internship.

Excuse me.

A. So that internship in internal medicine was a full year at Highland Hospital, which is one of the safety net hospitals in Oakland, California, and internal medicine is, broadly speaking, the field of medicine so it's front-facing, front line, you know, primary care treatment of people with medical illnesses.

Q. And then you did a residency in psychiatry, psychiatry being what you've already explained, but how -- what's the gamut, what's the range of psychiatry work that you studied and do?

A. I did a residency in adult psychiatry. This was a general residency, a broad-based clinical work in treating patients with a variety of mental illness.

Q. All right. And then after that, it looks like you did a two-year fellowship in mood disorders, psychiatry and behavioral sciences.

Can you tell us about that, please?

A. This was an additional time spent after my residency, specifically working with patients who

struggle with mood disorders.

Mood disorders include things like major depressive disorder and bipolar disorder.

Q. Okay. Your honors and awards, you probably don't want me to dwell on these too much, but you had a good GPA, that's what that means. Fair?

A. Yes.

Q. Outstanding teacher in structural biology.

What is structural biology because I will be asking you some of those questions today?

A. It's basically the study of disease at the cellular and tissue level.

Q. Okay. As I continue to look at your honors and awards, a couple more jump out at me that I'd like you to talk about.

The Fellowship Training Directors Award with the American Society of Addiction Medicine, would you tell us about that, please?

A. So in 2013, we started an addiction medicine fellowship in our program at Stanford.

This is an opportunity for young physicians to do an additional year learning how to screen and intervene for addiction, and general addiction is poorly taught in medical schools and residencies, although there's growing interest now in studying addiction.

So I am the program, the founding program Director of our Addiction Medicine Fellowship, and I was recognized by the American Society of Addiction Medicine for my work in that area.

09:38:20 Q. All right. And then another one that seems relevant to me for what we're talking about is the Hazelden Betty Ford Foundation Humanitarian Kelly Clark Spirit Award.

Can you tell us about that, please?

09:38:36 A. That is an award for recognition of my years of service in the field of addiction medicine.

Q. All right. If -- the next section of your CV has academic and clinical appointments, and you've talked to us about some of those.

09:38:53 But I'd like to go to the Outstanding Research in Severe Mental Illness Janssen Scholar.

Can you tell us about that, please?

A. That was an academic award during my residency. That was awarded by my department in recognition of my

09:39:15 research at that time.

Q. All right. And then if we continue on, you are currently the Medical Director for Addiction Medicine.

Can you explain what that is?

A. So that means that in addition to my clinical and

09:39:32 teaching and research roles, I also now have

administrative roles where I lead our Addiction Medicine initiatives in the Department of Psychiatry at Stanford University School of Medicine Hospital and Clinics.

Q. And starting last year, you're the Director of the Taube Youth Addiction Initiative in the Department of Psychiatry and Behavioral Sciences.

Can you explain that, please?

A. That is a new initiative we've launched in the past couple of years, specifically targeting adolescents and what are called transitional age youth, those 18 to 25 who are struggling with a variety of addictive disorders.

Q. All right. And, Doctor, you have a medical license. Is it on file with the appropriate authorities and up-to-date?

A. Yes.

Q. And by the same token, you have Board Certification, is that correct?

A. Yes.

Q. Would you explain to the jury, first, what is Board Certification, and then we'll look at what you have certification in.

A. After medical school, physicians do a residency which is specialized training in their medical field of choice. When they complete that residency, they sit for an examination called the Board examination, and if they

pass that exam, then they get Board Certification, which is acknowledgement of their acquired expertise in that medical discipline and which is often required for employment.

09:41:10 Q. And so are you Board Certified in psychiatry and neurology?

A. Yes.

Q. Neurology is what?

A. The study of the brain, as is psychiatry.

09:41:24 Q. And are you also Board Certified in addiction medicine?

A. Yes.

Q. And are you also Board Certified in preventive medicine?

09:41:37 A. No. I am Board Certified in addiction medicine under the auspices of the American Board of Preventive Medicine.

Q. So this Diplomate of the American Board of Preventive Medicine is addiction medicine?

09:41:50 A. Yes.

Q. All right. Now, if we were to go through the rest of your CV, which time will not allow us to do, we would see that you are an advisor at Stanford's Medical School for Addiction Medicine fellows, is that right?

09:42:14 A. Yes.

Q. You also do MedScholar advisory work, correct?
A. Yes.
Q. Would you explain to the jury briefly what that means when you say you are an advisor.
09:42:29 A. I have many mentees, medical students, Stanford undergraduates, residents, fellows, people who I mentor in their work and in pursuit of their career goals.
Q. You also do editorial work as a guest editor and a reviewer and an associate editor for several journals.
09:42:51 Would you explain to the jury what you do, what you're called upon to do there.
A. These are what are called peer-reviewed medical journals.
One of the ways that the medical profession
09:43:07 tries to ensure quality in their publications is to send those publications that are submitted by the authors out to a group of anonymous peer reviewers who read it and then weigh in on its merits and its worthiness for publication.
09:43:25 And as editor, I have been responsible for being on the editorial board, which is to say to oversee this process and maintain the integrity of peer-reviewed journals. And as a reviewer, I myself have peer-reviewed many, many articles over the years.
09:43:47 Q. And have you also reviewed articles in the various

journals that you've got listed? It goes on for a couple of pages in your CV.

A. Yes.

Q. And so without reading through all of them -- oops -- you've actually done work relevant to each of these journals?

A. Yes.

Q. And do you receive funding for research from various places?

A. Yes.

Q. All right. The next section beyond that is scholarly work.

Have you published?

A. Yes.

Q. I showed the jury the cover of this book in my opening.

Is this your book?

A. Yes.

Q. *Drug Dealer, MD. How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*, Anna Lembke, M.D.

Was this a best-seller?

A. Yes.

Q. And what caused you to write this book?

A. I became very concerned about the harm that doctors

were doing to patients, mostly unintentionally, in terms of overprescribing medications like opioids, leading those patients to become dependent, addicted, and in some cases, die from those opioids.

09:45:21 And what I observed was that this wasn't just a matter of a small subset of so-called pill-mill doctors, doctors who had lost their moral compass and were prescribing for profit, this was a wholesale shift in the way that doctors practiced medicine, beginning in 09:45:40 the late 1990s, that triggered a huge increase in opioid prescribing for minor and chronic pain conditions, leading to the opioid epidemic that we have today.

So this book was my effort to show the causes of that change in prescribing from inside of the 09:46:01 medical profession, focusing specifically on physician prescribers and what factors have led to so many well-intentioned, good, well-educated physicians to overprescribe opioids and, thereby, essentially instigate our current opioid epidemic.

09:46:27 Q. And that's not your only book, right?

You've got a brand new one that just came out.

When did this "Dopamine, Finding Balance in the Age of Indulgence" -- oh, hold on, it's "Dopamine 09:46:46 Nation, Finding Balance in the Age of Indulgence." When

did this book officially come out?

A. It came out in August.

Q. In August?

A. In August.

09:46:54 Q. And some of this book will also be relevant in your testimony, I'm assuming?

A. It is relevant in the sense that my testimony is founded on the idea that the oversupply of addictive substances is the major contributor to people getting

09:47:18 addicted to that substance.

Q. All right. Doctor, I'm about through with the personal aspect of these questions, but before I leave that, I want to ask you if I ask opinion questions of you today, the law allows you to only express those if you're

09:47:38 doing it within the reasonable medical or scientific probabilities of your expertise.

Do you understand that concept?

A. Yes.

Q. And will you agree to only offer opinions that are

09:47:55 based on reasonable probability within the medical or scientific arena where you are testifying?

A. Yes.

Q. In other words, you can't be guessing and throwing stuff out there.

09:48:07 Okay? All right. Thank you.

So with that stop on the road, let's go to purpose.

MR. BUSH: Your Honor, just one second. I want to note for the record that there are some limitations on the scope of the expertise --

09:48:21

COURT REPORTER: I'm sorry. I can't hear you. I can't hear you.

THE COURT: I've made prior rulings on this.

09:48:30

MR. BUSH: Thank you.

BY MR. LANIER:

Q. Ma'am, what I'd like to talk to you next about is the purpose.

What have we asked you to do in this case?

09:48:46

A. You have asked me to search for the truth of the matter as to whether or not the pharmacy defendants contributed to a public nuisance in Lake and Trumbull Counties.

Q. And there are areas where the Court has ruled you

09:49:05

are allowed to testify. I'm going to keep the testimony to those areas carefully, but will you be here to testify about whether or not the pharmacy -- I want to get it just the way you said it -- pharmacy defendants contributed to a public nuisance in these counties?

09:49:28

A. I'm sorry. Could you ask me the question again?

Q. Yes.

Are you prepared to testify about the truth of whether the pharmacies contributed to a public nuisance in these counties?

09:49:41 A. Yes, I am prepared to testify on that matter.

Q. And in that regard, I want to go to process, the next stop, and ask you what work have you done, how did you go about forming these opinions?

A. So I reviewed the peer-reviewed medical literature.

09:50:01 These are the articles that are published in the field in reputable journals.

Q. All right. Time out. I've got to interrupt and make sure I keep this in a Q & A form.

So you have reviewed peer-reviewed

09:50:17 materials.

Why is that important to do?

A. Well, peer-reviewed journal articles hopefully set a standard of quality that can be relied upon.

Q. And so did any lawyers tell you which ones to

09:50:39 review, or did you go out and do this search yourself?

A. I went out and did this search myself.

Q. And were you satisfied that you had a chance to do the literature search?

A. Yes.

09:50:52 Q. Is that something that's very standard for you to

do when researching your own articles or books?

A. Yes.

Q. All right. So you reviewed peer-reviewed materials.

09:51:04 What else did you do?

A. I reviewed documents regarding the pharmacy defendants' policies and procedures for assessing red flags.

Q. Now, this is a good time to talk about something

09:51:24 that we left out, and that is we talked about all of the things you are in your CV, but we did not talk about the things you are not.

Fair?

A. Yes.

09:51:39 Q. Are you a pharmacist?

A. No.

Q. Are you here to testify as a pharmacist?

A. No.

Q. Do you teach pharmacists?

09:51:57 A. Sometimes.

Q. Okay. Do you work for a pharmacy chain or a pharmacy?

A. No.

Q. Do you interact with pharmacists?

09:52:10 A. Yes.

Q. Do you have pharmacists call you as part of your practice?
A. Yes, on a regular basis.
Q. Do pharmacists call you about prescriptions you've written?
09:52:23
A. Yes.
Q. Do you engage with pharmacists?
A. Yes.
Q. Okay. But you yourself, not one.
09:52:34
Fair?
A. Yes.
Q. All right. So when you looked and reviewed these documents on policies and procedures and red flags, were you looking at them as a doctor who does the work you do?
09:52:52
A. Yes.
Q. Fair enough.
What else did you do?
A. I reviewed other material provided by counsel regarding this matter.
09:53:16
Q. Were we able to supply you with certain documents that involved various companies, businesses, people, that are relevant to this case?
A. Yes.
Q. And were you able to review those and determine
09:53:32
whether or not they had any relevance in your opinions?

A. Yes.
Q. All right. Now, I know once you've done all of this, ultimately you wrote this report that's, like, hundreds of pages long, but did you do anything else
09:53:45 before you wrote the report, or are we almost there?
A. I'm sorry, I don't quite understand the question.
Q. All right. What did you do next?
What else did you do in this process?
A. I reviewed -- I reviewed orders from the DEA and
09:54:04 the Department of Justice regarding criminal, criminal investigations of pharmacy defendants.
Q. All right.
MR. BUSH: Objection, Your Honor.
MR. MAJORAS: Objection.
09:54:19 MR. STOFFELMAYR: Objection.
MR. BUSH: I don't believe that's disclosed in her report.
THE COURT: Sustained.
The jury is to disregard that answer.
09:54:30 MS. SULLIVAN: And, Your Honor, on behalf of Giant Eagle I would just, if the Judge could just instruct the witness when she talks about defendants, if she could identify them as opposed to lumping them altogether.
09:54:41 THE COURT: That's a good point.

So, Doctor, because the jury has to consider the evidence against each defendant separately, if you're speaking about any defendant or defendants, you should identify them specifically so we know if your answer applies to one, two, three, or four of them.

09:54:58

Otherwise, we wouldn't be able to know.

Thank you.

THE WITNESS: Okay.

MR. MAJORAS: Your Honor, one final objection. John Majoras.

09:55:08

Objection with respect to investigations generally, whether she's reviewed them or not.

THE COURT: I told the jury to disregard the answer entirely, so --

09:55:17

MR. MAJORAS: Thank you.

THE COURT: -- Mr. Lanier needs a new question.

BY MR. LANIER:

Q. All right. Ma'am, after reviewing these materials, did you prepare a report?

09:55:30

A. Yes.

Q. And does that report contain your opinions that you're prepared to offer in this case?

A. Yes.

Q. In addition to preparing that report, have you

09:55:46

already testified in other opiate matters?

A. Yes.

Q. Tell the jury about your previous testimony.

A. I've testified in this court before regarding the very broad case that has been brought against opioid manufacturers, distributors, and pharmacies.

I've also testified in individual cases regarding the same matter at the state and county level for a variety of different states and different counties in the United States.

So I have been working on this case in one form or another since 2018 and have been retained as a medical expert witness in a variety of different cases.

And I have testified in those cases.

Q. All right. Fair enough.

And do you have your report with you today?

A. Yes.

Q. You've got your report up there?

A. Yes, I do.

Q. And then what I'd like to do now is spend the rest of our time with you on the findings that you have made, the conclusions that you have drawn.

Okay?

A. Yes.

Q. Oh, I left out something.

Have you ever testified before the U.S. House of Representatives on the opioid epidemic and ways to mitigate the harms from that?

A. Yes.

09:57:25 Q. And have you presented at numerous conferences before Governmental, professional, academic and lay audiences on these topics?

A. Yes.

Q. All right. Then with that, let's look at your

09:57:40 findings.

What I've done is I've tried to take each of your opinions and put it onto a card so that the jury can see it while you talk about it and I question you about it.

09:57:50 Okay?

A. Yes.

Q. The first one, opinion number one, you had said, "The addictive nature of medicinal opioids has been known for centuries."

09:58:07 I mentioned this to the jury in opening, but I'd like you to give evidence to it, so take a moment and tell us some of the salient points of history where the addictive nature of medicinal opioids has been known about.

09:58:23 A. So the -- both the medicinal properties of opioids

have been known for thousands of years as well as the potential for addiction to opioids.

The problem of opioid addiction really took off with the advent of technological progress and the ability to take opium, which comes from the opium -- the poppy plant, and distill out active ingredients making them, thereby, more potent.

So, for example, in the early 1800s, chemists figured out how to distill Morphine in the laboratory from opium, and Morphine is approximately ten times more potent than opium.

In the 1850s, the hypodermic syringe needle was invented and the hypothesis at that time was that if doctors administered Morphine through the hypodermic syringe, patients were less likely to get addicted to Morphine.

Q. By the way, was that true?

Did that work?

A. No. In fact, the opposite happened, that the hypodermic syringe, which is not surprising to us now, but was purportedly protecting patients, actually fueled their addiction, leading to a whole generation of individuals in the United States in the late 1800s becoming addicted to Morphine specifically through the hypodermic syringe, including many civil war soldiers but

also housewives and all kinds of people.

Q. How did heroin come about?

A. In the late 1800s, the Bayer Aspirin company said that they had discovered or formulated a new opium, a new opioid in the laboratory that would have all of the same medicinal properties as Morphine and opium, but would not be addictive.

This was an exciting new discovery that they advertised, and they named it after the German word for heroic or heroish and they marketed it beside baby aspirin over the counter as heroin.

And heroin, then, of course led to the narcomania of the early 19 --

Q. The what?

A. The narcomania.

Q. Narcomania, what does that mean?

A. It was a term that was used to describe rampant heroin addiction that occurred in the early 1900s as a result of over-the-counter dispensing, free availability of heroin.

Q. So you could just go to a drugstore and buy cough syrup with heroin in it?

A. Yes. That is correct.

And as a result of that, the Harrison Narcotic Act was passed in the early 1900s, effectively

banning heroin and making it illegal for distribution and sale, which led to a marked decrease in the availability of heroin and also a number of people who were getting addicted to and dying from heroin.

10:01:53 Q. So when the market availability decreased, did it affect the addiction level?

A. When the market availability decreased, the number of people getting addicted to heroin also markedly decreased.

10:02:09 Q. Okay. Now, throughout the 1900s after the Harrison Act in, I think, 1914, but after the Harrison Act, what was the catalyst for the next wave of opiate problems?

A. The next major wave of opioid addiction started, is essentially this opioid epidemic, which began in the late

10:02:33 1990s as opioid manufacturers primarily but also other members of the opioid pharmaceutical industry widely promoted the use of opioids in the treatment, not just at the end of life or perioperatively or with severe trauma, but for minor and chronic pain conditions.

10:03:01 Q. What are the common names of these drugs that were coming out in the late '90s, these opioids?

A. There was, like, OxyContin, Vicodin, Percocet, Percodan, Opana, Fentanyl. So Fentanyl is a prescription opioid that is manufactured entirely in the laboratory.

10:03:25 One of the salient features of the history

of opioids is how technology has progressively allowed us to create more and more potent forms of opioids.

So, for example, I told you Morphine is ten times more potent than opium. Fentanyl is 50 to a hundred times more potent than Morphine.

10:03:43

So we've seen a progression and an explosion, not just in the numbers and varieties of opioid-manufactured pain medication but also an increasing in potency to the point today where doctors can prescribe things like Fentanyl lollipops for their patients.

10:04:02

Q. Okay. I want to ask you to explain a couple of terms that you've just used and help us understand some evidence that's already been suggested will come in in this trial.

10:04:19

You're talking about Morphine and Morphine is how much more potent than the simple opium fluid?

A. Ten times.

Q. Ten times more potent?

And I'm comparing it to what?

10:04:38

A. Here you're comparing it to opium.

Q. To opium. All right.

A. But our usual standard of comparison today is to Morphine itself.

Q. That's what I was going to have you explain to us.

10:04:51

So Morphine is the standard comparison? In other words, how do these other drugs compare to Morphine, is that what you're saying?

A. Yes. That's right.

10:05:07 Q. And what is the abbreviation for that? What's the words for that?

A. Morphine milligram equivalents or MME.

Q. Morphine milligram equivalents, did I write it right?

10:05:26 A. That's right.

Q. And that's abbreviated as --

A. MME.

It's essentially a way of seeing how much a patient is taking by referencing everything back to

10:05:43 Morphine.

Q. So if I wanted to determine how much of a drug was dispensed, is there a difference between dosage and Morphine milligram equivalents?

A. Well, there are a couple of ways to look at how

10:06:03 much of a drug is dispensed. One way is to just count the number of pills.

The other way is to convert those pills to Morphine milligram equivalents, and the reason that that's important and useful is because it captures not

10:06:20 just the quantity of opioids but also their relative

potency.

Q. All right. So if we wanted to -- but if we wanted to see how many doses a pharmacy or a doctor prescribed or dispensed, how do you count doses?

10:06:49 A. Well, there are a number of different ways to count doses, and I think looking at it from both perspectives is important, counting the number of pills dispensed, but also counting MMEs.

Q. No question about that.

10:07:06 And I think, I'm not making my question clear.

So let me try it again.

Let's do this. Explain the MME of Oxycodone.

10:07:26 A. So Oxycodone is about 1. -- 1.5, basically ten milligrams of Morphine is approximately equal to about 15 milligrams of Oxycodone, I believe.

There are equivalency charts that you can use to make those analyses.

10:07:44 Q. And I won't hold you to precision. Give us general data. That works here fine.

Oxycodone, 1.5 MME. How about Fentanyl?

A. So Fentanyl, because it's so potent, is usually measured in micrograms, but it's 50 to a hundred times

10:08:03 more potent than Morphine.

Q. So it would have an MME of 50 to a hundred?
A. It's 50 to a hundred times more potent, yes.
Q. All right. So if we measure by MME, we'll know how strong the medication levels are.
10:08:24 If we're trying to figure out how many pills people are popping, we can count the pills.
Is that fair?
A. Yes.
Q. Great.
10:08:32 All right. So as you were walking through the history, you told us about Morphine.
Where does heroin fit into this?
A. In terms of --
Q. Is it as -- Oxycodonish, 1.5, Fentanyl, in the
10:08:51 middle? Where?
A. I think the potency of heroin is pretty close to Morphine. It might be a little bit more potent than Morphine.
Q. All right. So it's not on Fentanyl level?
10:09:02 A. No.
Q. All right. Now, we roll into the 1990s.
You've said the addictive nature has been known for centuries. How did people determine that it was addictive?
10:09:25 A. I mean it was obvious.

There were multiple epidemics, as I described.

Q. Are you going to be able to tell us -- preview here -- are you going to be able to tell us why addiction is -- what chemically is going on in the brain that brings this addiction about?

A. Yes.

Q. All right. We'll get to that, but let me ask you, first, about this next part of your opinion.

You said, "Recent misrepresentations of the safety and efficacy of prescription opioids reversed a century of appropriate restrictions on the use of these dangerous drugs, and substantially contributed to the current opioid epidemic."

Is that your opinion?

A. Yes.

Q. Is it -- would you agree with the statement that opioids are safe and effective, simply because the FDA's approved them?

A. Not -- not simply because the FDA has approved them, no.

Q. Explain what you mean when you talk about misrepresentations of the safety and effectiveness, efficacy of them.

And we'll get into details later of how

that happened, but just what do you mean by that idea?

A. So beginning in the late 1990s, there was a massive effort to reeducate the medical community around the safe and effective use of opioids.

10:11:03 And this reeducation campaign was funded and promoted by opioid manufacturers, and basically communicated some fundamental untruths or misrepresentations about opioids to the broader medical community, which in turn led them to believe that opioids 10:11:30 are safer than they really are and also more effective than they really are.

And those representations are as follows.

Number one --

Q. All right. Time out, because I've got to keep it 10:11:46 Q & A.

A. Okay.

Q. So what is the first misrepresentation?

A. So the first misrepresentation that was taught to the medical community is that as long as you are 10:11:59 prescribing an opioid for a person with pain, that they are very unlikely to become addicted to that opioid.

And there was even the implication that there was some kind of biological protection that having pain conferred to the vulnerability to becoming addicted 10:12:23 to that opioid. None of that is true, by the way.

But that is what doctors and others were taught during the late 1990s and really very late into this century, that a patient with pain prescribed an opioid by their doctor for pain was very unlikely to become addicted to that opioid or that it was very rare.

Q. All right. What is your second misrepresentation?

A. The second misrepresentation was this idea that no dose is too high.

So one of the selling points or promotional messages was that if you have a patient who seems to respond to the opioid, that is they say, "Wow, this really helped my pain but it stopped working," that it was perfectly okay then to increase the dose in an unlimited fashion to target subsequent pain relief.

And doctors were essentially told that there was minimal or no risk in going up on the dose.

Very often this message was communicated by comparing opioids to things like Tylenol by saying, you know, Tylenol is something that you can't keep going up on the dose because Tylenol can cause liver death, but for opioids, that's not true, the implication being that they were so much safer and that the dose was really unlimited, when in fact, we have a lot of data showing that the higher the dose and the longer that patients are on opioids, the more likely they are to get addicted to

the opioid and the more likely they are to die from the opioid.

Q. Are there any other recent misrepresentations of the safety and efficacy that come to your mind right now, other than these two?

A. Another really important misrepresentation was the idea that opioids are effective treatment for chronic pain.

In fact, there are no reliable studies showing that opioids work well for chronic pain.

Now, there is good evidence showing that opioids work short-term for short-term pain or what's commonly called acute pain, but if taken for longer than three months on a daily basis, opioids simply don't work very well.

People develop what's called tolerance where they need more and more to get the same effect over time, which requires escalating doses, which then contributes to the risk, such that the tipping point between risks, benefits and alternatives of opioids used daily long-term just isn't justified, based on the evidence.

Q. Now, Doctor, you've used a couple of words and I want to make sure that I understand the medical usage you're using.

When you said, "Opioids are effective for chronic pain," what do you mean by "Chronic"?

A. Chronic refers to pain lasting for more than three months, which is past the time of normal tissue healing.

10:15:53 Q. All right. And then acute pain is pain that lasts what?

A. Typically less than three months.

Q. All right. Thank you.

Any other misrepresentations that come to

10:16:09 your mind right now?

A. Another important misrepresentation was this idea that doctors and other health care providers could be able to tell who would get addicted to opioids prescribed by a doctor and who wouldn't.

10:16:29 In other words, there was this idea that a doctor could somehow determine who was at higher risk, when in fact, although that sounds like a really reasonable goal and something that, you know, we should aspire to, the reality is that right now we do not have

10:16:49 any reliable tools to predict who will and will not get addicted to opioids prescribed by their doctor.

And furthermore, the biggest risk factor for getting addicted to opioids prescribed by a doctor is dose and duration, so the longer you're on the opioid,

10:17:09 and the higher the dose, the more likely you are to get

addicted to that opioid.

And that dose and duration actually trump or overpower other common risk factors for addiction like a personal or family history of addiction.

10:17:25 Q. Any other misrepresentations aside from these four that jump out?

A. I think those are the main ones.

Q. All right. So if we continue with your opinion, you say, "Recent misrepresentations of the safety and

10:17:45 efficacy of prescription opioids reversed a century of appropriate restrictions on the use of these dangerous drugs and substantially contributed to the current opioid epidemic."

You've explained the restrictions that had

10:18:03 existed.

Explain what you mean by, "substantially contributed to the opioid epidemic," and I need to narrow your attention on this to, let's start with these misrepresentations that you've described.

10:18:22 How did those substantially contribute to the current opioid epidemic?

A. Those misrepresentations led prescribers to believe that they could prescribe opioids with minimal risk, and so they began prescribing opioids prolifically for not

10:18:51 just people with acute pain or people who are at the very

end of life or people who were experiencing trauma or surgery, doctors then were encouraged to and were duped into believing that opioids were safe and effective for almost any kind of pain.

10:19:11 So that led to an increased opioid prescribing, which then led to an increased supply of opioids in our communities, in medicine cabinets, in high schools, on the streets, which in turn made it very easy for people to become exposed to opioids, even beyond

10:19:34 people who were seeing a doctor and getting a prescription, which in turn led to several generations of Americans getting addicted to opioids and dying from opioids.

Q. I want to make sure I'm writing and charting what

10:19:50 you're saying properly.

You're saying that the increased prescribing led to an increase in supply, which led to an increase in exposure?

A. Yes.

10:20:10 Q. Which made it -- which led to several generations of addiction?

A. Yes.

Q. All right. Is this some of what you talk about in your book, *Drug Dealer, MD, How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*?

10:20:31

A. Yes.

Q. I think the, "Why it's so hard to stop" is in your next opinion, so I want to put your second opinion up and discuss that with you, please.

10:20:45 You say, "Addiction is a chronic, relapsing and remitting disease with a behavioral component, characterized by neuroadaptive brain changes resulting from exposure to addictive drugs."

I'll stop there and we'll do the last

10:21:09 sentence in a moment.

Are you prepared to testify as to why this is your opinion?

A. Yes.

Q. All right. Then let's get started.

10:21:16 What does it mean for addiction to be chronic?

A. Once people develop the disease of addiction, they usually struggle with that disease lifelong.

It doesn't mean they don't get better.

10:21:29 Treatment actually works and people do get better, but it means that it's a chronic illness just like diabetes is a chronic illness, just like heart disease is a chronic illness.

Q. Okay. Relapsing, what does it mean for it to be a

10:21:47 relapsing disease?

A. That means it's a disease that is characterized by periods of remission or recovery that can be interspersed, not always, but can be interspersed with periods of relapse where people return to addictive drug use.

Q. And then a remitting disease, what does remitting mean?

A. Remitting refers to episodes where that individual is not engaging in addictive drug use, sometimes called recovery or more colloquially referred to as sobriety.

Q. Or being clean?

A. We try not to use that terminology any more because it's considered stigmatizing, clean versus dirty, but, yes, that is common --

Q. All right. Sober.

A. -- terminology.

Q. So sober is the right word to use, someone is sober?

A. Well, even that is not the medical term that we're using now.

I will say that the language of addiction is in flux as we try to de-stigmatize the language.

We usually talk about people being in recovery.

Q. In recovery. So remitting means episodes in

recovery?

A. Yes.

Q. All right. Thank you for that. I learned something.

"With a behavioral component."

Explain what you mean by that?

A. That's a way of drawing similarities between the disease of addiction and, for example, the disease of Type II diabetes.

Both diseases are chronic relapsing and remitting diseases with a behavioral component. For Type II diabetes, the behavioral component is often related to diet and inactivity. For the disease of addiction, the behavioral component is the drug seeking, the drug taking, and the other behaviors around the disease of addiction.

Q. So is it fair for me to say that's drug seeking and more?

A. Yes. Drug seeking, drug taking.

Q. Got it.

Now, "characterized by neuroadaptive brain changes resulting from exposure to addictive drugs."

You're not in a position to be able to draw up there for everybody to be able to see, and in this age of COVID, I'm hesitant to ask His Honor to let you come

down here to draw and testify.

So, instead, if you'll explain to me what to draw, I'll try and draw it. And I've also got one of your pictures from your report, but I want you to please explain to us what it means to have "neuroadaptive brain changes."

And you might start with how the brain works.

So teach us. How does the brain work?

10:24:37 A. Right. Yes.

So this refers to the neuroscience of addiction and the changes that occur in the brain as a person is becoming addicted.

And some key things to understand is that 10:24:51 there is a neurotransmitter in the brain called dopamine.

Q. All right. Time out.

A. Okay.

Q. A neurotransmitter.

What is that?

10:25:01 A. So a neurotransmitter is a chemical in the brain that allows neurons to communicate with each other.

Neurons are the main type of cell in the brain. Neurons are these long, very long spindly cells that send electrical signals from one neuron to the next 10:25:22 neuron, creating electrical circuits, that allow us to

have our thoughts, emotions, behaviors.

Q. All right. So for those of us who are visual, we've -- maybe people have seen those pictures of a brain that's got all of these tendrils that just seem to grow out and connect to various cells.

10:25:47

Does this horrible drawing help at all explain what you're talking about?

A. Kind of.

Q. Okay. Sorry.

10:26:06

A. It does a nice job capturing that neurons are long cells, but one of the key features of neurons is that they don't actually touch end-to-end. There's a little space between the neurons. And that space is called the synapse.

10:26:25

And nature has done that for a very good reason. It allows chemical modulators to adjust the electrical firing between neurons.

So those chemical modulators are molecules that are called neurotransmitters that transmit signals in that synapse from one neuron to another.

10:26:50

Q. All right. I tried it again. I only did three of them. Is this any better?

A. Better, yes.

Q. All right. So instead of actually connecting one cell to the other, you said there's a gap that chemicals

10:27:05

can then step into and make the connection.

Is that right?

A. That's right. Yeah.

Q. And the chemical, that is the synapse?

10:27:18 A. That's the synapse.

Q. So the synapse is the gap.

A. Um-hmm.

Q. And those chemicals that get into the synapse and connect the neurons, those are called neurotransmitters?

10:27:35 A. Those are called neurotransmitters, and one way to think about neurotransmitters is to imagine that on the pre-synaptic neuron, there's a little pitcher throwing a baseball. That baseball is the neurotransmitter and the pitcher throws it to a catcher on the post-synaptic

10:27:55 neuron, who catches the neurotransmitter.

And that catcher's mitt is the receptor. You probably have heard that neuroreceptors, but that's a catchers mitt sitting on the neuron waiting to catch that baseball, which is the neurotransmitter. And in this

10:28:12 case, we're specifically talking about the neurotransmitter dopamine?

Q. All right. So one neurotransmitter will throw the baseball to another -- to a receiver, a glove.

A. One neuron, one neuron will throw the baseball,

10:28:33 which is the neurotransmitter, to the catcher which is

holding the receptor.

Q. You got four kids. One of your kids is an athlete?

A. Yes.

Q. I see where the analogy came from.

10:28:46 All right. We'll thank Elizabeth for this one.

So you've got the connections then being made.

What's the next thing -- you're doing a

10:28:59 neuroscience of addiction, I'm following you, but now I know what a neurotransmitter is. So go back, and you said neurotransmitters, what do they do?

A. Okay. So dopamine, there are many different neurotransmitters in the brain. There's serotonin,

10:29:14 there's norepinephrine. We're talking about dopamine because it's probably the most important transmitter involved in the process of addiction.

And there's a specific part of the brain called the reward pathway. And in the reward pathway,

10:29:30 there are a lot of neurons that deal in dopamine.

Dopamine is a very important neurotransmitter in that specific part of the brain.

Q. All right. I've got to interrupt you to see if I'm making sense of this in my head, in my brain.

10:29:46 So there are lots of different kinds of

neurotransmitters?

A. Yes.

Q. One of them is dopamine?

A. Yes.

10:29:53 Q. And that's the one you're going to be telling us about here shortly?

A. Yes.

Q. So in the illustration you used, is dopamine the baseball?

10:30:02 A. Yes.

Q. Got it. All right. So where does the dopamine come from?

A. Dopamine is made in our bodies.

Q. Okay. And the dopamine is used to connect the

10:30:21 neurons?

A. Yes.

Q. All right. In what way does dopamine connect the neuron, I mean what does that do, what is the dopamine connection?

10:30:33 A. So dopamine is the most important neurotransmitter in our experience of reward, motivation, and pleasure.

And one of the fundamental differences between substances that are addictive and most that are not is that substances that are addictive release a whole

10:30:56 lot more dopamine in the reward centers of the brain.

Q. All right. May be a stupid question, does my dog have dopamine?

A. Yes, your dog has dopamine. And when you throw a ball, the dopamine spikes, and when your dog gets the ball, it probably goes even higher.

When you give your dog a dog treat, that dog will have a release of dopamine. Really anything that's rewarding, motivating, enhancing.

Q. Is that a way that dogs can be trained?

A. Yes. Absolutely.

Q. Does it also train, then, a human being sometimes in similar ways?

A. Yes.

Q. All right.

A. It --

Q. So if, if I redo the drawing here, we've got dopamine as part of these connections. And explain why they are particularly important on issues of reward and motivation and pleasure.

A. So dopamine produces the pleasure that we experience with any reinforcing behavior, and of course, once we get that dopamine, then we learn that that behavior gives us that feeling.

And then we learn to do it again. So it's very important to the learning loop.

But when it comes to the process of becoming addicted, what essentially happens is that that addictive substance hijacks this motivational circuit and makes us begin to believe that we need that substance for survival; that it's as important to us as food, clothing, shelter, taking care of our children.

This is what we mean when we talk about the hijacked brain of addiction.

Dopamine evolved in our brains over millions of years to encourage us to approach pleasurable stimuli and avoid painful ones, but the problem is that -- and we were evolved that way so that in a world of scarcity, we would seek out food, clothing, shelter and a mate. But the problem is that today, addictive substances essentially take over that part of the brain and confuse the brain into believing that getting that substance is equivalent to food, clothing, shelter and a mate.

And it does that in large part through this process of neuroadaptation, which I'm happy to explain.

Q. All right. And I'm going to have you explain it, but first I want to take this drawing that you've got in your -- I think you use this in presentations, don't you?

A. Yes.

Q. Is this relevant to what we're discussing?

A. Yes.

Q. All right. So I'm going to put your drawing up there instead of mine, and ask you to explain why this teeter totter between pleasure and pain, and it looks like you've got me on some bad days here on one side and me on some good days on the other side.

Explain that, please.

A. So one of the most important findings in neuroscience in the last 75 years or so is that pleasure and pain are co-located in the brain. So the same parts of the brain that process pleasure also process pain.

And pleasure and pain work like opposite sides of the balance. So if you imagine that in your brain, that part of your brain which I called the reward pathway, there's a little teeter totter, like in a kids' playground. And when we experience pleasure, that balance tips one way, and when we experience pain, it tips the other.

But one of the overarching rules governing this pleasure/pain balance is that it doesn't want to be tipped for very long to the side of pleasure or pain, and the brain will work very hard to keep that balance level or what's called homeostasis.

So, for example, if I do something pleasurable for me, like eat a piece of chocolate, my

pleasure/pain balance tips slightly to the side of pleasure but no sooner has that happened, then my brain will want to restore a level balance. And here's the really important point: My brain does that by tipping an equal and opposite amount to the side of pain before going level again.

This is called the opponent process reaction.

Q. Called the what?

A. Sorry. The opponent process reaction.

Q. Okay.

A. I imagine this as right after I eat a piece of chocolate, a little gremlin hops on the pain side of my balance to bring it level again but the gremlins really like it on the balance so they stay on until it's tipped and equal and opposite or not to the side of pain, then the gremlin gets off and my balance is level again.

That gremlin represents the process of neuroadaptation; how the brain adapts to my having eaten a piece of chocolate which released dopamine in my reward pathway. And essentially what the brain does in response to a release of dopamine is it starts to downregulate my own production of dopamine and my own dopamine receptors.

So taking that example and extending it to somebody who takes opioids, they don't just get a little

tip to the side of pleasure, they get a great big tip. And if they inject it intravascularly, they get a really fast tip. Remember how much dopamine and how fast that dopamine is released contributes to the experience of getting addicted. So they release it very quickly and a whole lot, now I need a great big gremlin on the pain side of my balance to bring it level again but remember, that gremlin stays on until it's tipped to pain. That's the come-down or opioid withdrawal.

10:37:06 10:37:20

It can be extremely painful. But with time, days, to weeks, the gremlin hops off and homeostasis is restored.

Now, here's --

Q. One --

10:37:31

A. Oh, sorry. Just one more thing.

To understand the process of addiction, what you have to imagine is that when the gremlin is tipped here, that person is experiencing the universal symptoms of withdrawal from any addictive substance: Anxiety, irritability, insomnia, depression, and craving, intrusive thoughts, abusing.

10:37:46

Also in the case of opioids, that person is experiencing bodily pain, even if they don't have a pain condition, when they're in opioid withdrawal, they will experience bodily pain.

10:38:04

So if that person continues to take opioids over days to weeks to months to years, even if that opioid was prescribed by their doctor for chronic pain, they will end up with so many gremlins on the pain side of their balance that when they're not taking opioids, their balance will tip to the side of pain and they will be in withdrawal, they will be craving, they will be irritable, anxious, restless, not able to sleep, and very importantly, they then need to continue to take opioids, not to feel good or even to relieve much pain, but just to get out of abject misery, just to bring that balance level and feel normal.

And it can take a really, really long time for the brain to readapt. So once those gremlins are camped out on the pain side of the balance, that can last for weeks to months and in some cases, even years after a person has stopped using their drug of choice, which is exactly why people will relapse, even when their lives are so much better.

And this was, I think, really revelatory for me because it was hard for me to understand why someone with addiction, who stopped using and got their job back and got their spouse back and got their kids back, why would that person give it all up to use the opioid again, but the neuroscience of addiction explains

that the physiologic drive based on a balance chronically tilted to the side of pain is going to overwhelm moral compass, overwhelm future goals, it's all that person can do really to get through a day.

10:39:48 Q. All right. I want to make sure I've got this in ways that I can hold on to longer than today.

So an opioid is going to cause a dopamine dump or release that will go into the brain?

A. It's in the brain. This is happening in the brain.

10:40:11 Q. Happening in the brain. Got it.

And when that happens, you can derive pleasure from that?

A. Initially that experience will give pleasure or relieve pain.

10:40:25 So, for example, not everybody starts out with a level balance. Right? Some people are living with terrible pain, and so when they take an opioid, temporarily that opioid will relieve their pain, but what happens is with repeated use over many months, the

10:40:41 balance will compensate and that person will end up in some cases in even more pain than when they started.

Q. All right. So I go, I get a root canal, the numbing medication wears off, I'm in pain, I've been given an opiate.

10:41:02 I may not get high from the opiate because

all it's doing is bringing the teeter totter back to deal with the pain, is that fair?

A. That's exactly right, yeah.

Q. And then if I keep taking it, at some point in time, it may tip the teeter totter to where all of a sudden, I'm -- well, no, I messed up again.

I'm not sure I get all of this.

So let me ask it this way.

A. Let me interject, too, and say that a person in pain who takes an opioid may experience relief of their pain and also will likely experience psychological reinforcements. So those two aren't mutually exclusive. You can get relief from pain and also get relief from anxiety, get relief from depression, have more energy or be able to sleep.

Q. All right. That's what I was trying to get to.

Thank you.

All right. So if we look back at this opinion, now, addiction, lifelong -- is "chronic, relapsing, remitting disease with behavioral component, characterized by neuroadaptive brain changes resulting from exposure to addictive drugs," is that what you've been describing to us?

A. Yes. Those gremlins represent the process of neuroadaptation, how in response to a whole lot of

dopamine, the brain will downregulate its own dopamine and its own dopamine receptors to compensate for that.

Q. All right. In your report you gave us -- and the parties obviously -- a drawing -- not a drawing -- a picture that is out of the molecular psychiatry book that was entitled, "Dopamine in Drug Abuse and Addiction: Results from Imaging Studies and Treatment Implication."

Can you explain why you thought this relevant to put in your report for the Court?

A. This is a very famous study by Nora Volkow, and her team. Nora Volkow is the Director of the National Institutes of Drug Abuse. And what she did here was she took pictures in real-time of the brains of people, healthy controls, people who had not been using drugs, and those brains are on the left-hand side.

So ignore the words "Cocaine, meth, heroin and alcohol" because they don't apply to the brains on the left-hand side.

The left-hand side brains are the brains of healthy controls, people who don't use drugs.

And what Dr. Volkow and her team did was she measured dopamine transmission in the brain's reward pathway.

And in this picture you'll see that dopamine transmission is higher the redder the color. So

the more red there is, the more dopamine transmission there is.

And what you see in those, that column on the left, in those healthy brains, is that there's quite a bit of red, meaning that there's a nice, healthy amount of dopamine firing in the reward pathway of the brain, which is great.

10:44:12

We all have a tonic base line level of dopamine that is firing all the time. That is crucial for our survival. And when we do something that's rewarding, it goes up, and when it goes below levels, that's aversive or not rewarding.

10:44:30

Then she scanned the brains of individuals who had been addicted to drugs, and those drugs are listed on the left-hand side; the cocaine, the meth, the heroin and the alcohol. And those brains are pictured in the right-hand column.

10:44:47

And what you'll see in those right-hand column brains is that there's very little red, which means that there's below-normal levels of dopamine transmission in those brains.

10:45:03

Now, what's really important here is that these individuals stopped using their drug of choice two weeks before these brains were scanned. So there, you have a wonderful example of how the brain goes into this

10:45:27

dopamine-deficit state with addictive drug use.

And that dopamine-deficit state can persist even after people have stopped using drugs.

So two weeks after stopping using drugs, these individuals still were not firing dopamine at normal levels. They had a pleasure/pain balance that was tipped to the side of pain.

Q. All right. Every human being has the potential to become addicted.

Your Honor, this is a good breaking point?

THE COURT: Okay. I was going to ask you.

MR. LANIER: Yes.

THE COURT: Without breaking -- interrupting you.

MR. LANIER: Thank you, Judge.

THE COURT: All right. Ladies and gentlemen, we will take our midmorning break, 15 minutes.

Usual admonitions and then we'll pick up with Dr. Lembke.

(Jury out.)

(Recess taken.)

(Jury in.)

THE COURT: Okay. Please be seated.

We need the witness.

MR. LANIER: Yes, the witness.

THE COURT: We will not get much testimony without the witness.

MR. LANIER: I now call -- no.

THE COURT: Okay. Doctor, I just want to remind you you're still under oath from this morning, ma'am.

And you can take off your mask while testifying. Yes.

BY MR. LANIER:

11:09:38 Q. Dr. Lembke, just so the Court knows and the jury knows and the lawyers know and we're clear, we've not communicated with you at all during this break.

Is that fair to say?

A. That's right.

11:09:46 Q. All right. And obviously, it would not be proper to.

We're just following the rules, but I wanted to put it on the record.

All right. Before the break, then, we were

11:09:57 looking at your second opinion, and I moved to this last sentence on the page, but your opinion actually blends into more. I just didn't have room to fit it all on one side.

So let's pick this up. "Every human being

11:10:13 has the potential to become addicted. Some are more

vulnerable than others. Risks for becoming addicted include genetic, developmental and environmental factors, nature, nurture, and neighborhood."

I want to pause there and have you explain what you mean when you say these things that I've just read.

A. So with enough external stressors, anybody can get addicted, and an important external stressor, which is underappreciated, is simple access to a drug.

If you live in a neighborhood where drugs are sold on a street corner, you are more likely to try those drugs and more likely to get addicted to those drugs.

If you see a doctor who is free with their prescription pad when it comes to addictive medications, you're more likely to be exposed to that drug and more likely to get addicted to that drug.

Q. All right. So you continue your opinion to say, "When supply of an addictive drug is increased, more people become addicted to and suffer the harms of that drug."

What is the basis for your opinion?

A. This current opioid epidemic is a prime example of increased supply leading to increased exposure, leading to increased rates of addiction and overdose death.

But there are other historical examples, both showing that when drugs become more available, more people get addicted and die from them, and also when drugs become less available, fewer people get addicted and die from them.

Q. So what other examples can you give us so that we maybe have a reference point in our brain?

A. So a couple of historical examples include Prohibition, for example. So between 1920 and 1933 in the United States, the distribution and sale of alcohol became illegal, and what is seldom appreciated about that time period is that when alcohol was not readily available, the rates of public drunkenness and alcohol-related liver disease decreased by half, which is really a remarkable event when you look broadly at epidemiologic studies or what kinds of policies change disease outcomes, it's a very potent effect.

When Prohibition was reversed and alcohol again became more readily available, rates of alcohol, addiction, and related disease again began to climb, although they remained quite low through the '30s, '40s and '50s, and have recently increased again with increased exposure to alcohol.

Another example is example of soldiers in Vietnam who, while overseas, had ready access to various

forms of opioids, including opium, many became addicted with ready access, but the vast majority, when they returned to the United States, at a time when there were -- it was very difficult or more difficult to get
11:13:47 access to opioids, most of them, their addiction largely resolved.

So access is a really important aspect and a really big risk factor for addiction.

Q. All right. You continue to say that, "Prescription
11:14:04 opioids are as addictive as heroin," and I want to pause there before we read the rest of this sentence.

Explain to us, please, the basis for your opinion that "prescription opioids are as addictive as heroin."

11:14:24 A. So culturally we have this idea that heroin is much worse than other opioids, but in fact heroin is nearly identical to Morphine. It's diacetylated Morphine, Morphine with two acetyl groups added.

Q. The Court Reporter is going to shoot you and me
11:14:50 both --

A. Sorry.

Q. -- if we don't pause for those words for a minute because I doubt they are in her machine.

Heroin is what?

11:14:59 A. Diacetylated Morphine.

Q. Okay.
A. So it's molecularly almost identical to Morphine and in terms of the way that opioids work in the brain, binding opioid receptors which then trigger this cascade
11:15:17 leading to the dopamine release in the reward pathway, opioids are opioids are opioids. It doesn't matter whether you get them from a doctor or you get them on the street from a drug dealer.
Q. And then you continue to say, "The defendants'
11:15:36 conduct in promoting increased supply and widespread access to prescription opioids has resulted in an epidemic of opioid addiction and overdose death."
MR. BUSH: Your Honor.
Q. Now, I'd like to break that down --
11:15:57 THE COURT: Hold on.
MR. LANIER: Sorry.
THE COURT: This is where she's got to be specific.
MR. LANIER: Yeah, that's why I was going
11:16:03 to break it down, Your Honor.
MR. BUSH: Thank you, Your Honor.
BY MR. LANIER:
Q. So I'd like to break this down and talk about this word "Defendants" for a moment.
11:16:13 Is it fair to say, as you are using the

word here, you're talking much broader than simply these pharmacies?

A. Yes.

Q. Would you explain who you mean by that term "Defendants"?

11:16:28

A. In this context, I mean opioid manufacturers, opioid distributors, and pharmacies.

Q. Okay. And are you making a difference here between chain pharmacies and -- that are large or chain pharmacies that are regional? Are you making a distinction between mom and pop pharmacies and the smaller or larger chains? Are you making any distinctions at all?

11:16:46

A. I am focused on chain pharmacies.

Q. Okay. Within the framework of that, we've got Walgreen's, CVS, and Walmart in this case.

11:17:03

Are you -- have you focused on those three?

A. Yes. And Giant Eagle.

Q. So Giant Eagle as a regional chain instead of a national chain, you're including them in this?

11:17:21

A. Yes.

Q. Great.

So "Defendants' conduct in promoting increased supply and widespread access to prescription opioids has resulted in an epidemic of opioid addiction

11:17:35

and overdose death."

Do you give us in later opinions more specific details of how this was -- this behavior contributed?

11:17:47 A. Yes.

Q. All right. Then we'll save that for those and try to get those, if not before lunch, then at least right after lunch.

Let's go to opinion number three now.

11:17:58 And so everybody knows, you've got, like, 14 or so opinions, but we won't spend this long on all of them, right?

A. I defer to you.

Q. Okay. I'll suggest to you we won't.

11:18:17 But I need to get the ground work laid, please.

So opinion number three: "Opioid prescribing began to increase in the 1980s and became prolific in the 1990s and the early part of the 21st

11:18:34 century, representing a radical paradigm shift in the treatment of pain and creating more access to opioids across the United States."

Is that your opinion?

A. Yes.

11:18:49 Q. And this opinion, does it -- are these dates such

that they require us to focus on actions that go back several decades?

A. Yes.

Q. All right. Explain what you -- the basis for your opinion number three. I know you've given us some of that already, you don't need to be redundant, so anything you've not told us about, would you explain the basis for opinion number three, please?

A. So the 1980s was the beginning of the hospice movement imported from Europe, and the hospice movement was a movement that recognized that people were living longer and often dying in agony.

And there was a push at that time to make opioids more liberally available at the end of life, and this was a positive and a good and a humane thing.

But, unfortunately, what that led to, especially when, you know, corporate entities, opioid manufacturers and others got ahold of that message, was to promote opioids based on false science, some of which I've already talked about, especially beginning with Purdue in the late 1990s and the release of OxyContin.

And with those promotional efforts on the part of Purdue and others, there was, again, a complete and radical reeducation of doctors and other health care professionals and a shift in the way that doctors

prescribed opioids, such that they prescribed more of them, more often, and for minor and chronic pain conditions at ever-escalating doses because they were taught that no dose is too high.

11:20:52 And that essentially is what led to the current U.S. opioid epidemic.

Q. Now, one of the charts that you had put into your report is this chart that I'm now showing to the jury that you had entitled "CDC," is that the Center for

11:21:10 Disease Control?

A. Yes.

Q. Parallel increases in opioid sales, deaths, and substance abuse."

And you've got a chart, "Rates of

11:21:23 Prescription Pain Killer Sales, Deaths, and Substance Abuse Treatment Admissions From 1999 to 2010."

Can you explain this chart to us?

A. What this chart shows is that as the sales of opioids increased, quadrupling between 1999 and 2010, so,

11:21:50 too, in lockstep did the rates of addiction and overdose death increase.

Q. So the green line at the top is the increase in sales?

A. Yes.

11:22:06 Q. And then the purple line in the middle, the

increase in deaths?

A. Yes.

Q. And the bottom line, the increase in what?

A. Treatment admissions for opioid addiction.

11:22:21 Q. And you've got this chart you've selected, seems to range in dates from 1999 up to 2010 for at least the sales?

A. Yes.

Q. All right. So if we continue to move through this, 11:22:42 your fourth opinion is that, "Misrepresentations contributed substantially to the paradigm shift in opioid prescribing through misleading messaging about the safety and efficacy of prescription opioids."

Explain what a paradigm shift is.

11:23:12 A. A paradigm shift is just a broad term to describe a big change that happens.

And here what I'm referring to is the big change that happened in medicine beginning in the late 1990s as a result of these misleading promotional 11:23:33 messages that it was okay to use opioids for any kind of pain, at any dose, for any length of time when, in fact, that is not supported by the evidence.

Q. Dr. Lembke, we'll get into this later on, but are you the only one in the United States who holds these 11:23:56 views today, or is this fairly understood science?

MR. MAJORAS: Objection. Bolstering.

THE COURT: Overruled.

A. Yes. There are many reputed medical bodies that agree with this opinion.

11:24:21 This is not an outlier opinion.

Q. And I'm not asking you to bolster you.

I'm asking you because is this something that people who work with the distribution and the sales of drugs would be aware of if they were reading

11:24:38 contemporary literature on the subject?

A. Absolutely.

So in 2009, for example, which was already quite late into the epidemic, it was widely known that the number of people dying from drug overdoses exceeded

11:24:56 the number of people dying from motor vehicle accidents or from firearms, which was unprecedented in history.

This was out in the media. It was known.

Q. All right. You continued to say, "The misleading messages were disseminated through an aggressive sales

11:25:20 force, key opinion leaders, medical school curricula, continuing medical education courses, clinical decision support tools, professional medical societies, patient advocacy groups, the Federation of State Medical Boards, and the Joint Commission."

11:25:50 Did I read your opinion correctly?

A. Yes.
Q. Do you believe that to be true?
A. Yes.
Q. What is the basis for your opinion?
11:25:57 A. There is overwhelming evidence that Purdue Pharma and others intentionally went about influencing the practice of medicine by creating relationships with many different people in medicine, leaders in the field of medicine, regulatory bodies, other influential
11:26:23 organizations, paid millions of dollars to these leaders, to these organizations, to medical schools, in order to influence and bring about this paradigm shift that changed the way that doctors viewed opioids and the way that doctors prescribed opioids.
11:26:47 Q. And we'll get into this in more detail later, but as a pre-lunch appetizer, did you find Purdue Pharma, for example, and the other manufacturers, but Purdue Pharma particularly, working with some of the major chain pharmacies, Walgreen's and Walmart and CVS that are in
11:27:12 this case?
A. Yes.
Q. Another item you had in your report that a lot of us will recognize from going to the doctor is this pain assessment tool.
11:27:28 Would you please tell us why you put that

in your report and why it's relevant?

A. So beginning around 2001, doctors and other health care professionals were encouraged to use this pain assessment tool on every patient that walked into their clinic or their emergency room or their hospital in order to assess their level of pain.

And they were shown, patients were shown, still are shown this chart where zero was no pain and 10 was the worst possible imaginable pain.

And the use of this chart was correlated or went along with promoting pain as the fifth vital sign, which again happened in 2001 with the aggressive influence of Purdue Pharma and others, this idea that not only was it necessary to take a patient's blood pressure, heart rate, temperature, but it was also essential to ask every single patient whether or not they were experiencing pain and at what level, including patients who didn't come in for pain or who didn't appear to be in any pain.

And there are no data to support this, the use of this tool. There's no data saying that using this tool improves pain outcomes.

There are data showing that using this tool increases opioid prescribing, and it's just another example whereby Purdue Pharma and others heavily

influenced the practice of medicine, including promoting tools like this broadly across the country to choose the way that doctors were prescribing.

Q. All right. Doctor, I want to move to opinion number five.

11:29:24

And, Dr. Lembke, there we have, "Opioid distributors collaborated with opioid manufacturers and pharmacies to promote sales of opioid pills."

Now, let's talk about broadly, and then we'll talk about specific pharmacies and name them based upon your opinion, but, first, broadly, what are you talking about?

11:29:46

And then understanding I need to break down which pharmacies. Okay?

Broadly, what's your basis for believing this?

11:30:02

A. Broadly, what I believe is that it wasn't just the opioid manufacturers who promoted these misleading messages, changed the paradigm around pain and contributed to the supply, it was also opioid distributors, the people who transport opioids from the manufacturer to the pharmacies.

11:30:19

Q. The middle person is what I described them as in opening.

Is that --

11:30:33

A. Yep. That's good.
Q. All right.
A. And also opioid -- also the pharmacies.
Q. All right. And you understand that for these defendants in this case, for a period of time, for some opiates, they were distributors as well as dispensers or pharmacies.

Did you know that or is that --

A. Yes, I did know that.
Q. All right. So how did -- well, I think you give it here.

"Such coordinated efforts included programs to give away free samples of opioids."

Again, without going into the specific pharmacy chains that you're going to talk about, in general, on a national level, what programs to give away free samples of opioids are you talking about?

A. So free samples are just what they sound like.

These were coupons or certificates that allowed individuals to go to the pharmacy and pick up an opioid medication for free.

And that contributed to the oversupply problem and was facilitated and made possible through coordinated, shared coordinated efforts between opioid manufacturers, opioid distributors, and pharmacies.

Q. Okay. So if we look, then, you include the coupons to discount as well as free, so they had multiple kinds of coupons?

A. There were multiple types of coupons. Some of the coupons were for free drug. Some of the coupons were for discounted drugs, where patients could pick up a drug and pay less for it.

Q. "Promotion of specific opioid products under the guise of education."

What are you talking about there?

A. This is a type of collaboration where pharmacists were trained on a certain opioid product, and that in their interactions with patients at the pharmacy counter would naturally, as a result of that training, educate the patient consumer in a certain way about that product.

And specifically, the same misleading messages that were promoted to doctors overstating the benefits and understating the risks of opioids were also promoted to pharmacists. And so I think it's fair to say that pharmacists, many of them, were also duped as a result and as part and parcel of this paradigm shift.

Q. So one of the things -- is it a fair distinction to draw between pharmacists in some regards and the businesses or the companies that run the pharmacies?

A. It's an important distinction to make between

individual pharmacists and the corporate structure under which they're trying to do their job.

Q. Why?

A. Because based on the evidence that I have seen, at the corporate level, there was cooperation between pharmacies and companies like Purdue to mislead, not just patient consumers and physician prescribers, but also pharmacists about the risks and benefits; thereby, encouraging pharmacists to regard opioids as safer and more effective than they really are, which in turn would influence a pharmacist's ability to use their proper judgment to determine whether or not they should dispense a certain drug.

Q. And have you found evidence of this regarding CVS?

A. Yes.

Q. Have you found evidence of this regarding Walmart?

A. Yes.

Q. Have you found evidence of this regarding Walgreen's?

A. Yes.

Q. How about the regional Giant Eagle?

A. Yes.

Q. Is it your opinion that these activities increased the population of opioid users, dose and duration of opioid use, and the risk of opioid misuse, addiction,

dependence, and death"?

A. Yes.

Q. Now, have you focused on the individual pharmacies in these counties, or have you looked at the national scope?

A. I've looked at the national scope.

Q. So the jury can be clear, we don't want to mislead in the least, you have not focused on individual pharmacists at the individual stores in these individual counties.

Fair?

A. That is correct.

Q. You're looking at national policy or regional policies for the regional chain, Giant Eagle.

Is that fair?

A. Yes.

Q. Thank you.

Now, when you talked about, "These activities increased the population of users, dose in duration and risk of opioid misuse," there were some other charts that I want to plug in here that you had in your report.

The one that I'm showing now is the one that is labeled, "The dose in duration of prescription opioids are the strongest risk factors for OUD."

What is OUD?

A. Opioid Use Disorder.

Q. And what does it mean that, "The higher the dose and duration of opioids, the greater the risk of addiction?"

A. So opioid use disorder is synonymous, is the same as opioid addiction, and these are data showing that the biggest risk factor for becoming addicted to an opioid is how long you're on it and how high the dose is.

And that as the dose goes up, you're more likely to get addicted, and the longer you're on it, especially if you're on it for more than three months taken daily, you're more likely to get addicted.

Q. So if we go to the big print down at the bottom of this, it's got an odds ratio.

You deal with those things all the time. Most of us do not.

Doctor, would you explain to us, please, what is an odds ratio?

A. An odds ratio is a way of determining risk to a certain disease outcome based on exposure to a risk.

Q. Okay. So some people would more normally think of an odds ratio as I'm going to roll the dice, I have a one out of six chance, the odds are one out of six it is going to be a one.

Is that like an odds ratio in your science world, same type thing?

A. Yes.

Q. All right. So the odds ratio for opioid use disorder with chronic -- you said that's over 90 days -- use of prescription opioids, it shows none OR equals one.

What's OR?

A. OR is the odds ratio.

Q. Okay. So the odds ratio, if you're not taking it, the odds of you getting addicted, that's the base line, that's one.

A. Right.

Q. So low dose, if you're on one to 36 milligrams a day, I would assume it depends on what the drug is -- or, no, these are calculated in MMEs?

A. That's right.

Q. Excellent.

So one to 36 MMEs would be how many tablets of Oxycodone?

Do you remember? An Oxy 30, for example, would that be in this group?

A. Yes.

Q. So an Oxy 30 OR 14.92, what does that mean?

A. That means that a person who's taking that amount

of opioids is 14 times more likely to develop an opioid addiction than a person who's not taking opioids.

Q. And then if they bump up to 36 to 120 milligrams a day -- and actually, maybe I was wrong. That may be where the Oxy 30 is, just bumping that number. But the medium dose, OR equals 28.69, what does that mean?

A. That means that at that higher dose, that that person is 28 more times -- times more likely to get addicted than a person who is not exposed to opioids.

Q. Does this scientific study that you have referenced here -- by the way, I want to get the Oxy down.

Oxycodone is 1.5 MME?

A. Yes.

Q. So an Oxy 30 pill, 30 milligrams of Oxy, would be on this chart, 45?

Is my math right?

A. I think so.

Q. Okay. All right. Fair enough.

Let's keep moving. If math -- we'll leave the math out for now.

Okay. So you put this chart in there to indicate that you had another chart that was very similar, higher dosage, higher risk.

Can you explain this chart, please?

A. These charts are taken from studies looking at risk

of dying from an opioid, what's often called an overdose. In a way, though, an overdose is a misnomer because it implies that the person took more than they were supposed to but, in fact, people can die of opioids taking them exactly as prescribed.

11:41:29

And this, these are data showing that as the dose of the prescribed opioid goes up, the risk of opioid overdose death also increases.

Q. Okay. Thank you.

11:41:45

So with opinion five out of the way, let's look at opinion six next.

In opinion six, you said, "Pharmacies," and we'll talk about which ones because that's going to be important so I want you to be thinking of the four in here, if you've got specific testimony about them.

11:42:06

"Pharmacies leveraged their unique and pivotal position in the opioid supply chain to contribute to the unprecedented and unchecked flow of opioid pain pills into the community. They alone had direct contact with opioid manufacturers and distributors upstream, and patients and prescribers downstream."

11:42:34

Is that your opinion?

A. Yes.

Q. What is the basis for this opinion?

A. Pharmacies' or pharmacists' role in the closed

11:42:47

opioid supply chain is really unique in that they alone have not just contact with the manufacturers and distributors, but they also talk to patients, they educate patients.

11:43:10 In fact, patients have ranked pharmacists as among the most trusted professionals that they -- that they can consider compared to other types of professionals.

Consumers rank pharmacists as even more

11:43:27 trusted than doctors. Pharmacists also regularly communicate with physician prescribers, so they have many different points of contact, they're very influential, there's enormous trust placed in pharmacists. And so, therefore, they really did and do play this key role in

11:43:48 the opioid supply chain and are pivotal in appreciating whether or not opioids are being misused, overprescribed, diverted, combined with other drugs that might harm them.

Q. Okay. So when you speak of words like "Upstream" and "Downstream," you've got a pharmacy, you've got

11:44:18 patients, customers, and then you've got the manufacturers and you've got the middle folks, the distributors. They're more than a truck driver but I'm drawing a truck because they get it there.

So how is it that the unique position of a

11:44:46 pharmacy touches everybody?

A. I mean, pharmacies are really the hub in many ways. They interact on a business level, on a corporate level with distributors and manufacturers on a regular basis.

Individual pharmacists will get communications from manufacturers and distributors, and at the same time, pharmacists are patient-facing. You know, they have many touch points with patient consumers. They are educators, patients rely on them to be educated about their -- the drugs that they're taking.

And they have many interactions with prescribers as well.

Q. All right. Let me give you some examples or question you on some examples.

Do you know for a fact specifically that in this case, these national chain pharmacies, Walgreen's, Walmart and CVS, had direct contacts with manufacturers of opioids?

A. Yes.

Q. And is that as pharmacists as well as, as distributors?

MR. BUSH: Objection, Your Honor.

MR. LANIER: As pharmacies. Excuse me, Your Honor, I misspoke.

BY MR. LANIER:

Q. Is that as pharmacies as well as in their role as

distributors?

MR. BUSH: My objection was to that even though it's a fact.

THE COURT: I'm sorry, what's the objection?

MR. BUSH: It's not a fact. She's not here as a factual witness.

THE COURT: All right. Do you know?

BY MR. LANIER:

Q. Based on your opinion.

A. Can you repeat the question?

Q. Yes, ma'am.

Have you found evidence that indicates to you that Walgreen's, Walmart, and CVS have directly had contacts on a national basis with, for example, Purdue, a manufacturer of opioids?

A. Yes.

Q. Okay. You're a doctor, you write prescriptions, right?

A. Yes.

Q. I would assume some doctors similarly had contacts at least with manufacturers and patients.

Fair?

A. Yes.

Q. Maybe not distributors.

I don't know. Do you have contacts with distributors, do you deal with them?

A. No.

Q. All right. Let's go to opinion number -- well, before we go to another one, let me ask you this.

Based upon your experience, are there some areas where doctors know things that pharmacists don't know?

A. Yes.

Q. For example, when you're a doctor, are you able to do a full exam on a patient?

A. Yes.

Q. So if I'm writing what doctors know, a full exam includes a history?

A. Yes.

Q. And a physical examination, I would assume?

A. Yes.

Q. What else is there that doctors know about a patient and prescriptions that perhaps a pharmacy may not?

A. Doctors might have access to laboratory data that a pharmacist would not typically have access to, things like urine toxicology screens to test for the presence of drug in the urine, basic metabolic panels to determine aspects of metabolism related to taking certain drugs or

certain disease processes.

The pharmacist wouldn't have the physical impression and the collateral information that the doctor would get on that day at that appointment necessarily.

11:49:31 The doctor would have, potentially have access to other collateral information through family members or significant others or other providers that they may have contacted related to that individual's disease process.

11:49:50 Q. So other info from friends, family or medical records, other doctors?

A. Yes, or just if that's a long-standing relationship with the patient, the doctor has access to that relationship and what's transpired during that

11:50:12 patient/provider relationship.

Q. All right. Based upon your interactions with pharmacies, pharmacists, what do the pharmacies -- and I'm speaking here in terms of the patient himself or herself; I'm not speaking in terms of manufacturers of

11:50:33 opioids, et cetera -- so in terms of patients, what is it that the pharmacists, based upon your knowledge and understanding, would have access to that's either the same or different than a doctor?

A. Well, the pharmacist would have access to their

11:50:53 physical impression of the patient when the patient comes

to the pharmacy to get their prescription, which may or may not be on the same day that they got the prescription from the doctor.

Q. All right. So physical impression of the Rx date, we'll call it.

11:51:13

A. The pharmacist would not typically have access to history, physical exam, certain lab data.

The pharmacist would not typically have access to friends and family, unless friends and family accompanied that individual to the pharmacy.

11:51:33

And the pharmacist would not necessarily have a long standing relationship with that patient, although some pharmacists, because patients can frequent the same pharmacy again and again, in some cases, some pharmacists will develop close relationships with their patient customers.

11:51:50

Q. Now, do pharmacists have an ability to call doctors?

A. Yes.

Q. Do you get phone calls from pharmacists?

11:52:01

A. Yes.

Q. Do pharmacists, when they call you, talk about the exam findings or the lab data at times with some of your patients?

A. Well, we -- I mean, the pharmacist doesn't have

11:52:15

access to that data, but we might discuss it as pertains to what is ever -- whatever is relevant to the question that the pharmacist has or the doctor has and is also within the bounds of patient privacy.

11:52:38 I was also, just finish -- we haven't quite finished that list. I was going to add all the things that a pharmacist knows that a doctor doesn't, which I didn't get to yet.

Q. Oh, that would be great.

11:52:49 Tell us what a pharmacist knows that a doctor doesn't know.

A. So what a pharmacist -- pharmacist has access to, importantly, is their own data systems that could tell them, for example, whether or not the doctor that that

11:53:05 patient was seeing was a pill-mill doctor, somebody who was prescribing lots and lots of opioids, essentially exchanging opioids for cash.

So the pharmacist has access to prescriber-level data that an individual prescriber

11:53:26 wouldn't have.

For example, I wouldn't know, necessarily, that that patient was seeing a pill-mill doctor in addition to seeing me.

Also, there's a database called the

11:53:41 Prescription Drug Monitoring Database that pharmacists

and prescribers can check to see all of the prescriptions that that patient has obtained for a controlled addictive medication in a geographic region.

And if a patient were engaging in doctor shopping, that is going to multiple doctors to get the same or a similar prescription, if I, as the prescriber, check that database but the patient hasn't yet gone to the pharmacy to get it dispensed, then I wouldn't be able to see that they were doctor shopping.

There's a gap of time between when they leave my office with the prescription and when they go to the pharmacy to pick it up. And if in that gap of time they go to six or seven other doctors to get additional prescriptions for opioids, and then at the end of that process, go around to different pharmacies to pick that up, the doctor could never see that.

Q. All right. So what I've put down here, I've tried to list those that you've said.

They've got access to their own data, it might tell them if the doctor is a pill-mill doctor.

Prescriber level data.

And then you talked about the PDMPs, the Prescription Drug Monitoring Programs or the database, and you -- you said that that's something that the doctor also has access to, but it may be a different picture.

Is that right?

A. That's right.

There's this important gap in time between leaving a doctor's office with a prescription and actually going to a pharmacy and getting that drug.

Q. Explain to us, just to remind us, we spoke about it yesterday, but remind us again what is a PDMP?

A. A PDMP is a Prescription Drug Monitoring Program or Prescription Drug Monitoring Database, and different types of health care providers have access to this database, including prescribing doctors and pharmacists.

And this database, when you go on it, what you do is you look up the patient, so you look up the patient by their name, and then you can see a list of all of the prescriptions they've received for a controlled drug.

Controlled drug means potentially addictive drug like an opioid.

And that usually covers a certain geographic region, typically the state, and a certain period of time, depending upon how far back you check but usually it's within the year.

And that's very useful and I would even say essential for determining which patients are misusing and/or getting addicted to and/or diverting opioids.

Q. All right. So if I am a patient and I want to get extra doses of a drug, and so I go see one doctor and she gives me some Oxycodone for my pain, and then I go see another doctor like the next hour and he gives me some Oxycodone for my pain, then I hit a third doctor who gives me some Oxycodone for my pain, and then I take those prescriptions and maybe instead of filling one at one CVS or instead of filling all three at one CVS, I fill one at one, one at another, and one at a third, or I fill one, one day and then wait a few days or a week and then I fill the second or I fill the third, is that something that the pharmacies who have access to the data would be able to see, that the doctors would not?

A. Yes. And it's why it's so critical for pharmacists to check the PDMP before dispensing a highly addictive and potentially lethal drug like an opioid.

It's absolutely fundamental.

Q. Okay. If a patient is going to pay cash for their drugs, who's in a position to see that?

A. The pharmacist. Only the pharmacist would know how a patient paid for their drug, and whether or not a patient pays in cash is really important because patients who pay with cash, that is correlated with patients who are misusing and diverting prescription opioids.

And one of the reasons for that, the reason

to pay in cash, is because if you tried to use your insurance to pay, the insurance company will pick up on the fact that there's doctor shopping going on and potentially notify the prescribing doctor; whereas, if you pay in cash, you're less likely to be detected.

Pharmacists are also the only ones that can see that patients are traveling from far away. That, for example, you know, a patient who lives in Ohio may travel to Florida to pick up their prescription or may travel to a remote pharmacy somewhere within their state where they're less well-known.

Q. What about refusals to fill?

Do you know anything about those on a pharmacy level, or is that outside your ambit of personal experience and knowledge?

A. So refusals to fill are when a pharmacist has identified that there is some kind of red flag.

Red flag is a warning that the prescription may be violating the Controlled Substances Act; that is, it's not being used for a legitimate medical purpose or has not been prescribed in the context of a meaningful doctor/patient relationship.

And according to the Controlled Substances Act, a pharmacist has a responsibility to identify red flags, and a red flag would be, for example, a patient

driving from a remote distance or in some cases, you know, a patient who appears to be intoxicated or a patient specifically asking for certain opioids by their street name as they're given the prescription, there are lots of red flags.

12:01:01

And the job of the pharmacists is to identify that there's a red flag and then, importantly, investigate that red flag.

Sometimes after investigating a red flag, a pharmacist will decide, you know what, I thought that this was a concern, but it's really not; I've resolved that red flag. And then the pharmacist will go ahead and dispense that opioid to the patient.

12:01:11

But in other instances, the pharmacist may determine, you know what, my suspicion about this, this red flag, was actually correct and I think that this patient would be harmed. And that's really what it's all about.

12:01:27

Q. All right. Doctor, I want to finish this list. I've got two more to ask you about and then I'll warn you about one thing and we'll go to lunch, if His Honor allows it.

12:01:43

First, do you, as a Doctor, know whether or not an opioid patient is going to refuse opioid counseling from the pharmacist?

12:02:03

A. No.
Q. Would you include that as something unique to the pharmacist's knowledge?
A. Yes.
12:02:15 Q. Would you, as a Doctor, know if the patient goes into the pharmacy and instead of just handing the prescription, calls it by its -- the drug by its slang or street name; would you know that that's going on as a doctor?
12:02:33 A. No.
Q. Okay.
Well, with that, we're at a stopping point with this, but I'll ask you after lunch to give us some specific examples, please, of how these four pharmacies
12:02:47 were involved in these relationships with the manufacturers.
Okay?
MR. LANIER: And with that, Your Honor, we are at a great stopping point if that's appropriate.
12:02:57 THE COURT: All right. Thank you, Mr. Lanier.
All right. We'll break for lunch. Usual admonitions.
We'll pick up at 1:00 o'clock with more
12:03:04 testimony from Dr. Lembke.

So have a good lunch.

(Jury out.)

(Luncheon recess taken.)

(Proceedings concluded at 12:04 p.m.)

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WEDNESDAY, OCTOBER 6, 2021, 1:02 P.M.

(Jury in.)

THE COURT: Okay. Please be seated.

And, Doctor, I just want to remind you you're still under oath from this morning.

So, Mr. Lanier, you may continue.

MR. LANIER: Thank you, Your Honor.

DIRECT EXAMINATION OF ANNA LEMBKE (RESUMED)

BY MR. LANIER:

13:04:29 Q. Dr. Lembke, did you get some lunch?

A. Yes.

Q. You got energy?

A. Yes, hopefully.

Q. All right. Did your dopamine reactors work in your brain?

13:04:38 A. Yes.

Q. Is it possible for someone to be addicted to Diet Coke?

A. Yes.

13:04:44 Q. Thank you.

How about Chick-fil-A?

A. Yes.

Q. All right.

Doctor, before the break, we were looking at your sixth opinion, and we had started out with this

portion of the sixth opinion that I had highlighted as we had read it and discussed it with the jury about pharmacies leveraging their unique and pivotal position.

I want to finish that sixth opinion with you, and as I indicated before lunch, talk about some very specific examples with all four of the defendants that are in the courtroom today.

Okay?

To that extent, I've put your sixth opinion, or your opinion six, up in a bullet point form so that we can discuss it.

"Their coordinated efforts to create demand." Why did you put "Create demand" in quotation marks?

A. Because it's not true that doctors write prescriptions and then pharmacies simply dispense them.

That doesn't accurately characterize the nature of how things really work.

Instead, it's a -- it's a bidirectional communication and there are multiple influences that will go into a doctor writing a particular prescription, including, for example, the patient asking for a specific product or a specific product being on the formulary.

And those things can be influenced by -- certainly a patient asking for a specific product can be

influenced by their interactions with a pharmacist.

So there are things that a pharmacist and a pharmacy does that can influence what the doctor ends up writing a prescription for.

13:06:54 Q. Okay. Thank you for that explanation.

And then in that regard, you continue to say, "Coordinated efforts create demand included," the first bullet point, "Advertising specific opioid products at the pharmacy counter."

13:07:16 Do you see that?

A. Yes.

Q. Now, what I'd like to do, Dr. Lembke, in your report that you prepared, you've got these opinions but then you elucidate on them, you expand them.

13:07:29 Fair?

A. Yes.

Q. And if I put the expansions of your report up on the screen, would you be able to explain them to us?

A. Yes.

13:07:42 Q. All right. Then in that regard, I will do so and I will start with Page 77 of your report, which is on opinion six. And instead of going through the entire report, I'm going to go through a couple of sections that I've marked and see if we can segregate out and discuss

13:08:07 some of this.

MR. BUSH: Your Honor, we object to this. It's not appropriate to have the report admitted into evidence.

I'm sorry I'm sitting because I wanted to make sure I got near the mic.

MR. LANIER: And I'm not trying to --

THE COURT: He's not admitting the report but he can go through the report as a way of dealing with the testimony. So that's overruled.

MR. LANIER: Yes.

BY MR. LANIER:

Q. So, ma'am, you talked about the pharmacy defendants advertising specific opioid products, higher doses and longer duration at the pharmacy counter on Page 78.

Are you familiar with that part of your report?

A. Yes.

Q. So can you take -- you've got your report in front of you?

A. Yes, I do.

Q. So if you could, walk through a bit of the -- a bit of the support for your opinion that you have provided to all of the parties in your report here.

A. Yes.

Focusing on Page 78?

Q. Yes, ma'am, or, Doctor. Excuse me. I'm from Texas. I say "Ma'am," and that's not polite.

Yes, Doctor.

A. So, for example, on Page 78, talked about how in 2011, CVS published an educational services document describing a promotional campaign that they could launch within CVS Pharmacies on behalf of selected opioid manufacturers for a fee.

In other words, they were offering to opioid manufacturers, like Purdue, to market things like OxyContin from CVS Pharmacies.

Q. And would CVS make money by promoting the opioid manufacturer's opiates?

A. Yes.

So CVS would make money twice, so to speak. They would make money because they've asked the opioid manufacturers to pay them to launch this educational, quote, unquote, educational service, and they will also make money because they will be dispensing opioids and making money off of the opioids that they're selling.

Q. Now, you quoted some language from this brochure, and I'd like you to, first, would you read for the jury the language you quoted, and then I'd like you to explain why that was important language for your opinion.

A. Yes.

So it says here, "Communicate your product's unique clinical benefits to thousands of targeted individuals.

Get the medicine right with the right 13:11:29 educational communications."

That, that's really important because it shows that the pharmacies were not just dispensing these opioids like a vending machine that somebody puts in money and gets out the opioid. They were in the business 13:11:49 of collaborating, at the corporate level with Purdue Pharma and others, to sell these opioids, to promote these opioids.

Q. You note in the next provision that this illustrates how CVS Caremark employed tactics initially 13:12:07 introduced by Purdue Pharma.

What do you mean by that?

A. So Purdue Pharma was really genius in a very devious way in terms of their opioid marketing and opioid promotion.

13:12:30 They realized that the way to get doctors to prescribe more opioids and pharmacists to dispense them and patients to take them was to promote the same misleading messages we talked about under the guise of science.

13:12:49 In fact, there wasn't robust science or

really much of any science to support the idea that addiction is rare or uncommon in pain patients who take opioids, or that no dose is too high, or that you can tell who's going to get addicted and who's not, or that opioids are good treatment for chronic pain.

13:13:10

There is not reliable evidence for any of those things. And, yet, Purdue Pharma infiltrated medicine to convince the health care community that these things were true.

13:13:24

And what these documents show, which I cite in my report, is that at the corporate level, CVS collaborated in that campaign of misinformation.

Q. And so you continue to talk about how CVS Caremark used buzzwords like education and literature to give their promotional efforts the sheen of science without the substance of scientific accuracy.

13:13:49

Is that what you meant?

A. Yes.

Q. Okay. Explain, please, your next subpoint if you would, the one about CVS offered these services to opioid manufacturers for a fee.

13:14:03

A. So CVS was doing this for money, and they advertised that they could, for example, send a newsletter out to thousands of CVS pharmacists if the opioid manufacturer would pay them $40,000, or they could

13:14:28

strategically place information about a manufacturer's opioid products right next to the prescription counter for $220,000 a month, that would reach 7,300 stores.

They also had direct-to-consumer mailings, so CVS -- CVS Pharmacy, and pharmacies in general, have a lot of powerful information about patients.

They have names, they have addresses, they have the medication that the patient is currently being prescribed and dispensed, and that gives them enormous reach in terms of influencing patient consumers. And they use this information or propose to use it to engage in direct-to-consumer advertising with direct-to-patient mailers to their homes.

They also talked about these promotional messages being on patient receipts, so when you go and you get a receipt for your medicine, there would be little advertisements on the receipt, and again, this was all for a fee.

Q. Now, in your report, you are always careful to footnote all of your statements.

What do you mean by the footnotes?

A. The footnotes reference the actual documents themselves that I reviewed, and from which these various quotations and the information is drawn.

Q. And when I was talking to you this morning and I

said what is all of the work that you've done to prepare to give your opinions, and you talked about reviewing documents, are these those kinds of documents?

A. Yes.

13:16:27 Q. Okay.

Now, stepping aside from CVS for a moment, you've got several paragraphs here on Walgreen's?

What did you find and what are your opinions on what Walgreen's was doing in this same

13:16:42 regard?

A. So similar to CVS, Walgreen's offered to opioid manufactures like Purdue that for a fee of $25,000, Walgreen's would send promotional material about, for example, Purdue's OxyContin to 26,000 Walgreen's

13:17:10 pharmacists in over 7,800 retail store locations using their web-based platform.

So again, this is another data point showing that Walgreen's was in the business of advertising and promoting specific opioid products for a

13:17:30 fee.

This was the way that they collaborated at the corporate level with opioid manufacturers and essentially disseminated the same misleading messages that the -- that was going to prescribers, to individual

13:17:48 pharmacists as well.

Q. Okay. But I've got a question.

If all that CVS or Walgreen's was doing was telling patients about the medicines and their availability and how they worked, how does that drive demand of the medicines?

A. There have been a lot of studies on this issue, and these studies consistently show that when you engage in what's called direct-to-consumer advertising in any form, you promote a specific brand of a medication to a patient, that patient is more likely to ask for that medication.

Likewise, direct-to-prescriber promotional efforts result in the prescriber being more likely to prescribe that medication.

So these are well-known and effective strategies for influencing what medicine gets prescribed, creating the demand for a specific medication.

Q. So the advertisements we all see for prescription drugs, even though I can't write a prescription for myself, I see that advertisement, are you saying there are studies that indicate that that will drive me to go ask my doctor for it?

A. That's right.

Q. Okay. Then look at the next paragraph on Walgreen's where you talk about how Walgreen's allowed

Purdue sales reps to make calls on Walgreen's health care supervisors who oversaw various sizes of retail stores.

What are you talking about there and why is that a problem?

13:19:43 A. So sales reps are people who are employed by the manufacturer of a given drug to go out typically to doctors's offices and promote that drug.

And for example, in the case of Purdue Pharma, Purdue Pharma hired people who were called sales 13:20:05 reps or drug reps, whose entire job was to go out into the fields, again typically we think of those individuals as going to doctors, to promote prescribing of, for, in this case, or for example, Purdue's product, OxyContin.

But what is really important and also was 13:20:28 very surprising to me in my research was that Purdue sales reps were allowed by Walgreen's to promote OxyContin, Purdue's product, to Walgreen's health care supervisors, who oversaw 70 to a hundred retail stores.

And this was supposedly to, quote, unquote, 13:20:56 provide pharmacists education material to their pharmacists through corporate coordination, including branded and unbranded resources to reach 27,000 pharmacists.

So Walgreen's colluded, excuse me, colluded 13:21:16 in and participated in the promotion of OxyContin, and

they did that by allowing drug reps to meet and promote OxyContin to their pharmacy health care supervisors who, in turn, would then promote OxyContin to the pharmacists who were working in the stores.

13:21:41 Q. And then, Doctor, as you conclude this paragraph, you said, "Furthermore, this relationship was a quid pro quo. In return, Walgreen's provided Purdue with data on OxyContin purchases at the store level."

What are you talking about there?

13:21:59 A. Yeah, so one of the ways that -- one of the ways that Purdue would benefit from this collaboration with Walgreen's was not just that their sales reps would go and promote OxyContin to pharmacists, but also Walgreen's agreed to provide Purdue with specific store-level data

13:22:29 about how much OxyContin they were selling and dispensing.

And again, that's another example to show that Walgreen's, at the corporate level, was actively cooperating and collaborating with opioid manufacturers

13:22:48 like Purdue to promote specific products in return for money.

Q. In your next section, you talk about how, "Pharmacy defendants mailed promotional material directly to patients and prescribers."

13:23:03 And I'd like you to address with us,

please, this first paragraph where you talked about the manufacturers, including Purdue and Actavis, contracting with a company called Adheris, for prescription adherence programs.

13:23:20 What's a prescription adherence program?

A. A prescription adherence program is a program that works to get patients to stay on a certain medication.

Q. And this is one that was offered to retail pharmacy chains, including you've got Giant Eagle and Walmart with

13:23:50 a footnote.

Do you -- is that based upon what you have researched and read?

A. Yes.

Q. Is that a good thing or a bad thing?

13:24:00 A. In the midst of an opioid epidemic, these adherence programs contributed to the oversupply and to people being harmed by opioids.

Q. And the oversupply and the harm, is that only from pill-mills and diversion, or is it a greater problem than

13:24:21 just that?

A. It's a greater problem than just that.

Q. So if the jury hears about studies that indicate a lot of people get their start by taking extra drugs from the medicine cabinet at home, maybe because they think

13:24:37 it's okay or whatever, is that part of the problem here?

A. Yes.

So a big aspect of the current opioid epidemic is not just the harm that was done to individuals who were directly prescribed the opioids and overprescribed the opioids or prescribed in dangerous ways, it's also, very importantly, just the simple fact that so many opioids flooded our society that opioids became easily and widely available to people who hadn't gotten the prescription themselves.

13:25:17 So teenagers rifling around in their parents' or grandparents' medicine cabinets, just being experimental, looking for something to use recreationally with friends; not necessarily people who are addicted or people who have pain and are seeing a doctor, but really

13:25:36 innocent people who take a very high dose, potent opioid, because they're teenagers and because that's what teenagers do.

And then end up dying from that.

This is a key piece of it. It's the sudden

13:25:54 and ongoing increases in opioid prescribing in counties across America that led to this oversupply, this flooding, that then harmed people, not just those receiving the prescription, but also anybody who had access to it, including people who were not addicted,

13:26:14 importantly including people who were just experimenting

or including people who were physically dependent and not addicted.

Q. All right. If we continue to look at what you've said about this with this Adheris program, a 2013 agreement between Purdue and Adheris detailed a year-long Directadhere program for Butrans.

What is Butrans.

A. Butrans is Buprenorphine in a patch formulation that is FDA-approved for the treatment of pain.

Q. Is it an opioid?

A. Yes, it's an opioid.

Q. Okay. You have in here the goal behind it, and then you have the agreement notes that the program will be offered to the retail pharmacy chains in the Adheris Pharmacy Network, which included Walmart and Giant Eagle.

Is that true?

A. Yes.

Q. Why was that important to you to put into your report?

A. Because again, when it comes to opioids, you don't need and shouldn't have adherence programs.

Opioids sell themselves.

The real challenge is getting patients who have been on opioids off of them again. There's no difficulty keeping patients on opioids.

So an adherence program like this is really just about business. It's about promoting that product so that the pharmacies could continue to sell that product and make a profit.

13:28:02 Q. When you include in here this language, "Templates of the letters submitted for Giant Eagle's approval had a Giant Eagle letterhead and optional language regarding the savings program," can you read the quotation and tell us why that was important from a Giant Eagle perspective?

13:28:22 A. The quotation says, "The Butrans savings card allows eligible patients with a valid prescription for Butrans to save up to $50 on each prescription after paying the first $15."

And the fact that the letter was submitted

13:28:38 on Giant -- Giant Eagle's letter template, again, just shows that Giant Eagle was not just dispensing pills; they were involved in promoting and selling these products and worked directly with opioid manufacturers like Purdue to promote specific products.

13:29:03 MS. SULLIVAN: Objection, Your Honor.

I move to strike. Lacks foundation as to whether the letter was actually mailed by Giant Eagle.

THE COURT: Overruled.

BY MR. LANIER:

13:29:18 Q. Ma'am, you also spoke about in your report an

agreement that called for 37,500 projected letters to be mailed to an estimated 15,000 Kadian patients.

What is Kadian?

A. Kadian is long-acting Morphine.

13:29:41 Q. So it's an opioid?

A. Yes.

Q. You continued to say, "The program was to be offered to all the pharmacies in Adheris Pharmacy Network, which included Rite Aid, Walmart, and Giant

13:29:52 Eagle."

Is that based upon your research?

A. Yes.

Q. Then you picked up on a six-month analysis of the adherence program.

13:30:12 What did that indicate to you?

A. That analysis showed that these adherence programs were very effective; that patient consumers who were exposed to the pharmacy adherence program compared to control patients were more likely to maintain that opioid

13:30:37 for a longer period of time.

They were 5.2 percent more likely to remain on the therapy, and 1.4 percent more likely to return with a new prescription.

Now, again, really important to remember

13:30:52 that when you're talking about treating chronic pain with

an opioid, the evidence supports short-term use. There is not reliable evidence to support people being on opioids taken daily for long periods of time.

Q. Now, if we go back to your main opinion, number six, "In addition to coordinated efforts to create demand, including advertising specific opioid products at the pharmacy counter," you have said "Building opioid Super Stores to enhance unrestricted flow of opioid pain pills."

What do you mean by that?

A. So Walgreen's collaborated with Purdue to create Super Store pharmacies, and these pharmacies essentially became the pill-mill equivalent of a pharmacy.

They were pharmacies that people could readily get opioids at, and the scrutiny of possible red flags was reduced.

The supposed point of these was to make sure that patients who really needed opioids got them. And, of course, that is important and we want to make sure that people who need opioids and who can benefit from them have access to them.

But that is not the kinds of collaboration that was going on here. These were really business, business-driven collaborations that were in the business of selling as many opioids as possible.

Q. And in that regard, when you fleshed this out in your report, this idea of building Super Stores, I'd like to direct your attention to Page 83, your comments at 11 and 12, Roman Numeral 11 and 12, and ask you about what you mean by these and why it's important.

13:33:07

Look first at 11. Would you read to us what you wrote in eleven?

A. Yes.

So this was a series of internal e-mails

13:33:25

that I reviewed between Purdue corporate representatives regarding Walgreen's pharmacy, and Eric Perham from Purdue, he was a Purdue sales rep, wrote to his manager, "Today was a great day for pharmacy calls," and then the e-mail went on to describe the interaction between

13:33:50

Purdue's Eric Perham and Bob Brody, a Walgreen's pharmacist.

Q. And in this regard, can you put a date on this for the records sake? It's in your report.

A. This was February, 1997.

13:34:04

Q. All right. And then the follow-up paragraph, what were you explaining to us in that one, please?

A. So this was basically Bob, Walgreen's pharmacist Bob Brody, recommending what they would do to create these Walgreen's opioid Super Stores.

13:34:27

They -- he said specifically that they

would increase their inventory of narcotics, narcotics here refers to opioids, eight-fold in these specific areas; high prescribers would always have an adequate inventory, which is concerning because high prescribers can and often do include pill-mill doctors or people who are prescribing in dangerous ways; not always, but often.

And then just really importantly, at the bottom, that the doctors will have the assurance that the pain meds will be filled by a pharmacist less likely to question his or her prescribing habits.

In other words, they were creating stores where patients could fill opioid prescriptions without much scrutiny, which is very troubling because it means that these stores essentially became, you know, a funnel for more opioids.

Q. All right.

Now, in this same section of Super Stores in your report, you continue to say, in Paragraphs 18 and 19 on Page 85, two points that I'd like you to testify about; the first one, tell us what these documents also attest to as per Walgreen's role in assuring the availability and how that promotes a specific product.

A. Another part of this agreement between Walgreen's and Purdue was that Purdue agreed that if a given pharmacy experienced a loss of OxyContin due to theft or

robbery, that they would replace opioid stock without increasing safeguards to mitigate any kind of diversion, which is extremely concerning because if you have a pharmacy where there's theft or robbery, that is a pharmacy that needs closer scrutiny, needs more safeguards, needs better systems in place to make sure that that theft or robbery doesn't happen again.

If you don't do that at the same time that you just restock that pharmacy with opioids, you are contributing to the problem of oversupply.

Q. Dr. Lembke, if we continue to look at your opinions in your report as we put them in the demonstrative, what I've listed as a third bullet point is, "The coordinated efforts to create demand included spreading misinformation about the safety and efficacy of opioid pain pills."

Is that also your opinion?

A. Yes.

Q. Do you hold that opinion today?

A. Yes.

Q. And if we look at how you elucidated that opinion, I've marked a couple of paragraphs for you to testify about, if you don't mind.

You say pharmacy defendants, but are you able to specify which ones?

A. Yes.

Q. All right. In terms of spreading misinformation about the safety and efficacy, why is that a bad thing?

A. It all contributes to the paradigm shift in opioid prescribing, whereby the medical profession went from recognizing that opioids are highly addictive, even to patients being prescribed them, and that they need to be used cautiously and sparingly, to prescribing them in high doses, long duration, high volume, for all types of pain.

And this paradigm shift occurred not just among prescribers, but also among pharmacists.

And pharmacy education was provided by the pharmacies themselves. They opened their door to Purdue and others to come into their pharmacies and teach their pharmacists the same misleading messages that they had been actively teaching to prescribers.

And that's really important because pharmacists themselves also then didn't appreciate the true risks and benefits of opioids and so weren't able to use real science to inform their judgment about when to dispense, about investigating red flags, about how far it was necessary to go to investigate the red flags.

Q. In this regard, you give some details in Paragraph 2, Roman Numeral 2, you say --

MR. BUSH: Objection, Your Honor, if I may be heard.

Graeme Bush, I'm sorry.

THE COURT: Let's go with the headphones.

13:40:05 (Proceedings at side-bar:)

MR. BUSH: Can you hear me, Your Honor?

THE COURT: Yes. What's the objection, please?

MR. BUSH: This is a document that we were
13:40:15 going to deal with this morning and plaintiffs withdrew the document so we did not actually address it, but it is a document that comes from Purdue's files. It was hearsay upon hearsay and reflects a meeting, the substance of a meeting that apparently or at least this
13:40:31 document reflects may have occurred at Purdue.

It is not authenticated. There is no basis to even show that it's a genuine document.

But even if it were authenticated, it's got multiple levels of hearsay.

13:40:45 It's relating what actually happened at the meeting. If you read the rest of the --

THE COURT: I don't have the document. No one's given it to me. Apparently --

MR. BUSH: Yeah. Sure. Sure, Your Honor.

13:40:56 THE COURT: Plaintiffs agreed they were not

using it so I don't know why if plaintiffs agreed they were not using it, why it's being used.

MR. BUSH: We have another one. We'll get you one. Just one second, Your Honor.

13:41:06 THE COURT: Mr. Lanier, if you all went through this this morning, and you agreed not to use it, it shouldn't be used.

MR. WEINBERGER: Your Honor, this is Mr. -- this is Pete Weinberger.

13:41:16 We did -- we said we weren't moving to admit it at this time.

We didn't say we weren't using it.

MR. BUSH: I'm sorry, Your Honor. I'm having a little trouble hearing Mr. Weinberger.

13:41:27 THE COURT: All right. He said -- he said they agreed not to admit it.

If this is a document Dr. Lembke reviewed, Mr. Bush, she's entitled to say that she reviewed.

You can point out that it's not reliable,

13:41:39 it's hearsay.

She reviewed it.

MR. BUSH: Actually, Your Honor, I think the law in the Sixth Circuit is that you cannot use an expert to get an inadmissible document into evidence and

13:41:51 that's in substance what they are doing.

THE COURT: They are not moving it into evidence.

MR. BUSH: They are in essence moving it into evidence, Your Honor. They are citing exactly what it says.

13:41:59

MR. LANIER: Your Honor, it's the support for her opinion.

THE COURT: Well --

MR. LANIER: That's why she's allowed to rely on it and you're allowed to cross-examine her exactly as you said.

13:42:14

We're not moving it into evidence off of this, nor are we trying to. We're just trying to elucidate the basis for her opinion which has been in her report.

13:42:30

THE COURT: Well, the problem with this, Mr. Lanier, is that this is the reviewed document that purports to say what Purdue did with CVS.

We don't have anyone really here to authenticate that that happened.

13:42:42

The other document that she was testifying to was a CVS document. She said she reviewed agreements which CVS produced. There was no dispute about that.

MR. WEINBERGER: Your Honor, at the hearing 30 days ago before Special Master Cohen, this document

13:42:55

was on the list of documents that we covered, and we produced at that time a certification pursuant to the Rules from Purdue that this was a business document kept in the ordinary course of --

13:43:16 THE COURT: All right. I'm going to -- I mean, with that, with that basis, you can use it and, Mr. Bush, you can cross-examine that she has no, no knowledge that it's not -- that it's legitimate.

MR. BUSH: Your Honor, I mean the predicate 13:43:33 of that, of your ruling and of what Mr. Weinberger just said is incorrect.

The affidavit that came from Purdue does not even come from Purdue, it comes from an outside counsel with no personal knowledge whatsoever of this 13:43:42 document.

And it's not a proper basis to authenticate it.

THE COURT: It's a lawyer from Purdue that says it's an authentic document.

13:43:52 MR. BUSH: It's an outside counsel from some law firm.

THE COURT: That's a lawyer. What does that mean?

MR. BUSH: Just what I said, it's a lawyer 13:43:58 from an outside counsel for Purdue purporting to certify

that this is an authentic document for his client.

He has no basis to do that.

THE COURT: Wait a minute.

You're an outside counsel for your client, right?

MR. BUSH: But I haven't certified the authenticity of anything. It's not my -- I'm not at issue here.

THE COURT: Well, but, you're speaking for your client right now.

That lawyer was speaking for his client or her client.

MR. BUSH: As a matter of evidence, it's not proper to have somebody with no personal knowledge who isn't even a person at the company certify it.

THE COURT: I'm overruling the objection.

You can cross-examine. You can say, you know, Dr. Lembke will have to admit she has no idea where this came from, and, you know, I think I will -- it's not being admitted as evidence. It won't come in as evidence. All right?

And I'll instruct the jury that this is -- this document is not coming in as evidence, but if Dr. Lembke reviewed it, she can say it formed the basis of part of her opinion and you can cross-examine on it.

MR. BUSH: But, Your Honor, perhaps if she said that there was such a document, it's the basis for her opinion or part of the basis for her opinion, that might be something.

13:45:18 But she's actually reciting the contents of the document.

THE COURT: All right. I'm not going to let her do anything until -- unless she says that this helped her form the basis of her opinion.

13:45:30 Show it to her without showing it to the jury and see what she says.

MR. LANIER: All right.

(End of side-bar conference.)

MR. LANIER: May I continue, Your Honor?

13:45:49 THE COURT: In the manner which I allowed.

MR. LANIER: I understood that.

BY MR. LANIER:

Q. Dr. Lembke, the memorandum that summarized this meeting, did you rely upon that memorandum in forming

13:46:07 your opinion that pharmacy defendants, specifically CVS, spread misinformation about the safety and efficacy of opioids?

A. Yes.

Q. Was this an important aspect of support for your

13:46:24 opinion?

A. Yes.
Q. And was the language in this, and what was conveyed in this memorandum from 20 years ago, important language for you to consider in forming your opinions?
13:46:40 A. Yes.
Q. Okay.
MR. LANIER: And with that, Your Honor, may I then ask her why and have her indicate the language that was important to her?
13:46:50 THE COURT: Yes.
MR. LANIER: Thank you, Judge.
BY MR. LANIER:
Q. Then, ma'am, what I'd like you to do is please tell us why -- well, first of all, explain the language that
13:47:02 was important to you. And by important to you, I mean it formed, in part, the basis of your opinion.
What is that language, please?
A. The language that is important to forming my opinion includes statements like, "Ensuring the
13:47:31 availability of OxyContin," because again, in the context of an opioid epidemic, simply ensuring availability without proper safeguards is not adequate.
We all care about patients who need opioids getting those opioids, but when there's not proper
13:48:06 systems in place to detect diversion and misuse and

dangerous prescribing, especially in the context of an opioid epidemic, then simply ensuring availability is a danger to individuals and to the public health.

Also, there is a statement here from Barry Jasilli, CVS Director of Quality Improvement, so again, making an important distinction here between representatives from these pharmacies who are in leadership roles, who were in corporate leadership, as distinct from individual pharmacists working on the front lines, and this is one more of many examples of corporate leadership essentially colluding and cooperating with opioid manufacturers like Purdue.

Here, the Director of CVS quality improvement indicated that he felt Purdue was being victimized by the situation, and that's -- that's a quote here or that's a quote from, from the communication from the senior executive at Purdue that the product is not the issue; that the abuser is the issue, and that from his perspective, the perspective of the CVS Director, we, Purdue, should be fighting back even harder.

So this --

Q. Why is that important in your opinion?

A. This is really important because one of the very early strategies of Purdue Pharma to promote OxyContin was to say that OxyContin is not the problem; the problem

is those addicts who are ruining it for all of the legitimate pain patients; those bad guys, those evil actors, those yucky addicted people are the ones who are making it impossible for our legitimate pain patients to get what they need.

13:50:14

And, in fact, that dichotomy does not exist. Legitimate pain patients get addicted. People with addiction are human beings who deserve to be respected and deserve to have their addiction identified and have access to treatment.

13:50:31

So when you have a CVS Quality Improvement Director saying that Purdue was being victimized, that the product is not the issue, that the abuser is the issue, you're really propagating an untruth about who gets addicted and you're also justifying a system that says all We need to do is just identify those bad folk, you know, those bad addicts, and we don't need to pay attention to anything else. We don't need to pay attention to the oversupply problem. We don't need to pay attention to these patients on really high doses. We don't need to pay attention to patients who get prescribed opioids and Benzodiazepines like Xanax simultaneously because those are all legit real patients.

13:50:53

13:51:13

But those patients are the ones, many of them, that went on to get addicted themselves or somebody

13:51:33

in their family did because they had so many opioids in their medicine cabinet.

Q. All right.

Ma'am, moving on, in the meeting, you've made another note about CVS agreeing to post-diversion brochures on their Intranet site.

That sounds like a good thing to me.

Why is that not a good thing?

A. It does sound like a good thing, but if you actually read the brochure that Purdue created, that CVS was now disseminating to all the pharmacies, it really minimizes the breadth and scope of the problem and tries to paint the problem as a small subset of, quote, unquote, addicts as opposed to the really much more significant problem of oversupply, of flooding of our communities, of millions of pain pills making the entire society at risk.

Q. The jury heard in opening statements reference to another aspect of this that you've got here and that is the Paragraph 7, Roman Numeral 7 on Page 87, the June, 2001 letter to CVS pharmacists announcing CVS's participation in "Partners Against Pain," sponsored by Purdue Pharma.

Why is that part of your opinion?

A. So Purdue Pharma was involved in creating what are

called front groups.

These are organizations that appeared to be independent of Purdue Pharma but were, in fact, created by Purdue Pharma, funded by Purdue Pharma, and became basically the means by which Purdue Pharma promoted opioids.

13:53:25

And it is significant to note that CVS promoted one of these front groups to their pharmacists, this front group was called "Partners Against Pain" and again, it was an organization that existed to promote opioids using all of the same misleading messages that we've been talking about.

13:53:45

And this letter that went out to CVS pharmacists, which was created by CVS, went so far as to call Purdue, "A leader in educating the health care community on effective pain management and the appropriate use of pain medicines."

13:54:01

Q. When you say this was created by CVS, what do you mean by that?

A. I mean that it was made at CVS corporate headquarters, it was on CVS letterhead, CVS corporate mailed it out to CVS pharmacists, promoting an organization that repeated these untruths like the risk of addiction is low in patients with no history of substance use, that there's no tolerance to

13:54:19

13:54:48

opioids -- which is simply not true. Most people taking an opioid daily will develop tolerance, meaning they'll need more and more over time to get the same effect.

Q. You've got an excerpt from the CVS "Partners Against Pain" website from March of 2001.

13:55:12

The excerpt that you've got here in your report on Page 87, subsection eight, was that an important part in you forming your opinion about spreading misinformation about the safety and efficacy of opioid pain pills, vis-a-vis CVS?

13:55:31

A. Yes.

Q. All right.

I would like you to, then, explain, first would you show us the language that was important to you and then I'll have you explain why it was important.

13:55:45

MR. BUSH: Your Honor, I believe Mr. Lanier misspoke and said the CVS Partners Against Pain site, website. And that's really Purdue's.

THE COURT: I'm sorry?

13:55:59

MR. BUSH: I'm sorry if you couldn't hear me.

THE COURT: No.

MR. BUSH: I believe Mr. Lanier just misspoke and said the CVS's Partners Against Pain website. It's actually Purdue's.

13:56:06

I just wanted that to be clear.

MR. LANIER: If I did, Your Honor, I'll fix that.

THE COURT: Next question, please.

13:56:14 MR. LANIER: Yeah.

BY MR. LANIER:

Q. You've talked about how CVS sent a June, 2001 letter to CVS pharmacists announcing CVS's participation in Partners Against Pain sponsored by Purdue Pharma.

13:56:26 Right?

A. Yes.

Q. And then in that regard, you have an excerpt from the Partners Against Pain website that was three months earlier than that letter, March of 2001.

13:56:40 Correct?

A. Yes.

Q. And I'll ask you the same question to be sure I'm clear and the record's clear. Is this language that you saw on that website from March of 2001 which forms part

13:56:54 of your opinion that they were spreading misinformation about the safety and efficacy of opioids?

A. Yes.

Q. All right. With that, I want to show you the language and ask you to tell the jury, please, and the

13:57:07 Court why language was important to you that formed part

of your opinion.

A. So starting with the quote where it says, "The majority of physicians and nurses fear that opioid use will result in addiction, drug tolerance, and uncontrollable side effects, especially respiratory depression," this is right from Purdue's primary playbook about how to promote OxyContin, basically to say that anybody who wasn't prescribing opioids for pain was inappropriately afraid of things like addiction, things like people not being able to breathe, which is how people die from opioids, right?

Breathing slows down, heart rate slows down, people fall asleep and don't wake up again.

So essentially what Purdue did and what Partners Against Pain was continuing was to say -- was to, in effect, shame health care providers for their inappropriate fear or what was sometimes called opioid phobia, their inappropriate fear of prescribing opioids or in this case, dispensing opioids to patients for pain.

You'll also note that this quote says, "The risk for addiction is low in patients with no history of substance abuse."

In fact, there are data showing that approximately a quarter of individuals with chronic pain who take an opioid long-term will develop misuse or a

mild opioid addiction, and approximately 10 percent will become severely addicted to opioids.

So it's clear that the risk for addiction is not low, and although it is true that those with a history of addiction are more likely to get addicted to opioids prescribed by a doctor, the biggest risk factor is dose and duration of opioid.

That is much more important when it comes to who's going to develop addiction and who won't than personal past history of substance use. And in fact, we have no reliable ways to predict who will and will not get addicted through a doctor's prescription.

Q. Toward the end of this paragraph, you have noted how the memo touted CVS's long history of having a positive relationship with Purdue, the benefit of the program to both organizations, and how the continuing education series would contribute significantly to our strategic business goals.

Why is that language that you would include in your report?

A. Again, really important to recognize that at the corporate level, CVS Pharmacy was collaborating with and cooperating with Purdue Pharma for business reasons.

They wanted to make money together, and this is how they partnered to do it.

Q. All right. Now, in addition to CVS, you've got sections here where you're explaining your opinion of spreading misinformation about safety and efficacy, you've got sections in here on Walgreen's, is that correct?

A. Yes.

Q. And if we look at Paragraph 14, you reference a -- let me hold this up first -- a December, 1998 letter to Walgreen's pharmacy supervisor, Scott Diveney, D-I-V-E-N-E-Y, in Paragraph 14.

Is this a significant document where you've relied upon the content to form your opinion?

A. Yes.

So this is another example whereby at the corporate level, Walgreen's pharmacy opened their doors up to Purdue and let Purdue, quote, unquote, educate their pharmacists about opioids.

And we know that Purdue's so-called educational efforts were really promotional efforts based on misleading messages.

Q. And so if we consider Walgreen's, do you think it important for your opinion that Walgreen's is -- have their pharmacy people being educated about opioids by Purdue?

A. Yes.

It means that Walgreen's pharmacists on a national level were being fed the same false and misleading messages about opioids that doctors were during that same time period, contributing to the paradigm shift in opioid prescribing and dispensing, which led to the current opioid epidemic.

Q. Well, you speak of a Purdue-sponsored continuing education program.

What, for those who don't have a lifestyle where continuing education programs are important, what is one of those within the framework of what you're testifying to?

A. So continuing education is the education that physicians and pharmacists must continue -- must continue to engage in on an annual basis in order to maintain their professional credentials.

These are often conferences or sometimes they're lunches or dinners, but we are required to get a certain amount of continuing education credits per year in order to continue to practice medicine, or in this case, continue to practice pharmacy.

Q. The CE program for the pharmacists was entitled "Use of Opioids, a Pharmacist's Responsibilities."

To me that sounds like a good program that would be very helpful.

Why do you have it down as misinformation?

A. A Purdue-sponsored program about opioids is going to be a program about opioids full of misinformation.

Q. You then go on to talk about an August, 1999 letter, almost a full year later, to the Walgreen's pharmacy supervisor where Purdue offered to fund another continuing education program.

Do you believe the funding of these continuing education programs by Purdue are evidence of a coordinated effort to create demand?

A. Yes.

Q. And by the same token, you've also got provisions in here about Walmart.

Is that fair to say?

A. Yes.

Q. If we continue to look through this, we continue to see Page 91, Paragraph 22, Walgreen's, you say that Walgreen's executive, Sheila Bennett, was giving Purdue executive Stephen Seid, S-E-I-D, inside information on how Walgreen's trains its pharmacists, allowing Purdue to reach a larger target audience than it otherwise would have.

Why is that an important part of your opinion?

A. That establishes that leaders within the Walgreen's

corporation were actively collaborating with and cooperating with Purdue Corporate to promote opioid products.

Q. And then you cite a memo revealing further that Walgreen's -- and this is Roman Numeral 25 -- "Walgreen's, based on its own data, which it shared with Purdue and is reproduced below, was able to see that as the dose of OxyContin tablets went up, so, too, did the number of pills dispensed."

14:06:08 Now, I want to ask you what you mean by that, and I'll show the chart that you have put into your report here and have you explain it, please.

A. So what this chart shows is that as the strength of the OxyContin pill went up from 10 to 20 to 40 to 80 to

14:06:31 160 milligrams, the number of prescriptions went down so fewer people got those very high dose prescriptions compared to the lower dose ones.

But importantly, the average prescription size, so the quantity of pills dispensed, went up at the

14:06:57 highest doses. And that is very concerning because we do know that the more potent the opioid is, and of course OxyContin 160 milligrams is like 16 Percocets in one pill, that that is going to release an enormous amount of opioids in a person's body deceptively in one pill, and

14:07:24 then added to that, as these pills' potency got greater,

the Walgreen's pharmacists were dispensing larger quantities of them.

So the people who are most at risk because of the size and potency of the OxyContin pill, the 160 milligrams, were also getting larger numbers of pills, putting those individuals at very serious risk for overdose and death as well as addiction.

Q. All right.

In Paragraph 30, you talk about the New Trends course program which was delivered to Walmart pharmacists and elsewhere, being replete with misleading messages about opioids, taught by individuals who were on Purdue's Speaker Bureau, and receiving consulting fees from opioid manufacturers?

Why is that an important part of your opinion?

A. So again, this was a part of Purdue's strategy. They would identify people who were leaders in the field, in this case Neil Irick, and Purdue would pay these individuals to help them create these courses on opioids and go around and teach these courses on opioids.

And I've reviewed many of these types of courses, and they contain all of the same misleading messages about opioids.

And what I learned, based on these

documents, is that this New Trends continuing medical education course taught by Purdue Pharma's key opinion leader, Neil Irick, was presented to Walmart pharmacists.

So that is an important example again showing that pharmacists themselves were also duped by Purdue with permission and even encouragement from Walmart.

Q. Now, your bullet points continue.

In the interest of time, I'm going to leave out, "Partnering with pro opioid industry advocacy and lobbying organizations," but I'd like to get to the next bullet point where I've enumerated your concern about ignoring red flags for misuse and diversion, including concerns expressed by their own pharmacists.

Do you see that?

A. Yes.

Q. All right. In that regard, can you explain what you mean by that?

A. As the opioid epidemic began to unfold and more and more people were getting addicted to opioids and dying from opioids due to the oversupply, the red flags started to mount.

And, remember, red flags are the things that a pharmacist by law has a responsibility to investigate because they are suggestive of misuse,

diversion or just a dangerous drug-drug combination.

And what I discovered in reviewing these materials is that not only were frontline pharmacists not given the necessary tools to identify and investigate red flags by their corporate leadership, but when pharmacists themselves went to their managers and to corporate leadership to express concern and worry that they had about the way that opioids were being dispensed in their stores, that corporate leadership woefully ignored pleas from pharmacists and implicitly encouraged them to ignore those red flags.

Q. All right. Let's go through and look to see it if --

MR. STOFFELMAYR: Objection.

THE COURT: Hold it.

MR. STOFFELMAYR: May we have a side-bar before we go further?

(Proceedings at side-bar:)

MR. STOFFELMAYR: Judge, can you hear me?

THE COURT: Yes.

MR. STOFFELMAYR: I have two concerns about this line of questioning.

One is this goes into areas that are beyond the areas of pharmacy practice you said she could testify about in your *Daubert* decision.

You said she was, you know, qualified to identify red flags, talk about why they were important and what they mean, but now we are getting into the internal operations of a pharmacy and whether they were 14:12:24 effective, which is not an area in which she has any experience.

The second point is I'm pretty sure I know where she's going with this, and what Mr. Lanier is going to have her do is read out loud the entire content of a 14:12:38 clearly inadmissible e-mail, which I understand your point that she can talk about inadmissible evidence but she can't be put on the stand to simply read out loud an inadmissible e-mail for the benefit of the jury.

THE COURT: I mean, all these documents 14:12:54 were cleared for authenticity, all right, with Special Master Cohen so they're authentic.

He's not putting the documents in. I don't know, you're saying it's inadmissible. It may or may not be.

14:13:05 He's not offering it. She's relied on it in her report. We've seen the report. If she's relied on it, she can talk about it.

Now, she can only -- she cannot talk about internal pharmacy, pharmacists, pharmacy practices but 14:13:23 she can certainly talk about red flags.

MR. LANIER: Your Honor, the direction I was headed with this is from Page 13 of your *Daubert* motion ruling where you said she can testify to the efficacy and effects of the defendants' policies and procedures, such as ignoring red flags.

Page 13, you said that was in.

THE COURT: Right.

MR. LANIER: What you said was out on Page 13 was the time that it would take pharmacists, the resources that it would take pharmacists, and the incentives that were provided to pharmacists.

I've read your *Daubert* ruling very carefully. I will avoid those.

You also threw out any idea that we can argue that the marketing from anybody was causation in this case, and I'll avoid that as well.

MR. STOFFELMAYR: Judge, if she testified as she's about to that an employee complaint was ignored, not properly handled, that it reflected something about the internal workings of the pharmacy that were improper, that goes exactly --

THE COURT: I mean, I'm not going to let her opine about the internal workings of any particular pharmacy.

All right? Or any particular store. She

knows nothing about that. She said she hasn't analyzed any particular store.

MR. STOFFELMAYR: What she said is she's going to testify about complaints being ignored by pharmacists.

14:14:43

That is exactly about the operation of particular stores; not about red flags in general.

MR. LANIER: Your Honor, I understand your ruling and I'll walk that --

14:14:56

THE COURT: All right. We're --

MR. LANIER: -- exactly the way you've said.

THE COURT: All right. We're going to stick to my ruling.

14:15:04

MR. STOFFELMAYR: Thank you, Judge.

(End of side-bar conference.)

BY MR. LANIER:

Q. All right. Dr. Lembke, in this regard of ignoring red flags for misuse and diversion, including concerns

14:15:28

expressed by their own pharmacists, I want to leave the concerns expressed by their pharmacists aside for a moment and, instead, what I'd like to talk to you about and direct you to are the things -- thank you, Frank -- are the things you had to say about specifically

14:15:46

the *Holiday CVS* case in this regard.

And you talk about that on 10 -- Page 106 of your report. If you could turn to Page 106, please.

Roman Numeral 9, you start talking about -- oh, I just lost this monitor.

14:16:23 MR. LANIER: Your Honor, we've lost all of our monitors over here.

MS. SULLIVAN: Mr. Lanier, is this too far if I turn it?

MR. LANIER: Oh, thank you, Ms. Sullivan.

14:16:37 I can't remotely see it.

MS. SULLIVAN: I can move it.

THE COURT: Robert, can you see what's going on?

(Pause.)

14:17:16 THE COURT: Robert, can you get IT up? What's the issue?

MR. LANIER: Your Honor, in the interests of time, I think I might be able to see off of that table and I've got the small --

14:17:33 THE COURT: All right. We are calling IT people to come up and address the monitors.

MR. LANIER: All right. But I think I can continue without this monitor and keep us on your schedule.

14:17:41 THE COURT: Great. Thank you.

MR. LANIER: Thank you, Judge.

BY MR. LANIER:

Q. Okay. Doctor, you talk about the *Holiday* case.

Can you tell the jury a little bit about your understanding of what the *Holiday* case is, and why it was important to you?

A. The *Holiday CVS* case was important, number one, because it involved CVS Pharmacies and CVS is a defendant in this case.

And, number two, because it was a very carefully done investigation over several years in Florida, really documenting that these pharmacies, these CVS Pharmacies in Florida, were systematically ignoring red flags and, thereby, contributing to the opioid oversupply problem.

And, in fact, the DEA then revoked the DEA license from two Florida pharmacies based on their investigation.

Q. All right. And in that regard, you speak about it in your report, and you spoke of the CVS -- *Holiday CVS* case involving a number of different red flags at that CVS Pharmacy.

What is your understanding of -- that goes into your opinion of why this is important information for you and the jury?

A. Well, this is important information because according to the Controlled Substances Act, pharmacies not only have a responsibility to identify red flags and investigate them before dispensing, but pharmacies have a responsibility to create a system that will effectively detect red flags and support their pharmacists in doing so.

So it's --

MR. BUSH: Your Honor, I think this is outside the scope of both her opinion and her expertise.

MR. LANIER: This is her opinion, Your Honor.

I mean, this is her report.

THE COURT: Overruled.

A. So importantly, it's really a dual responsibility.

It's a responsibility to detect red flags and act on them, and it's a responsibility to create a system that will allow the pharmacy to do that.

And --

Q. And -- I'm sorry.

The reason I'm asking you this, and I want to make sure that we put it clearly in the record in light of the objection, is you go on to talk about how, for example, a red flag for the combination of opioids and Benzos should have been in place no later than 2007

based on medical literature and no later than 2010 based on DEA enforcement actions.

Is that a red flag that you're talking about?

14:21:07 A. Yes.

Q. And as a doctor who understands the brain and the way these drugs work and publish on them, can you explain why a combination of an opioid with a -- what is a Benzodiazepine?

14:21:25 A. A Benzodiazepine is a sedative hypnotic drug.

Q. A sedative hypnotic drug?

A. Yes.

Q. So it's like a chill pill?

A. Yes, you could say that.

14:21:39 And it includes drugs like Xanax, Ativan, Valium, Klonopin.

One of the big responsibilities of pharmacies is to identify dangerous drug combinations, and part of their independent and corresponding

14:22:05 responsibility is to do that.

You've probably had the experience or maybe someone you know has gone to the pharmacy to pick up a medication and have been told that it has an interaction with another drug that that person is taking.

14:22:15 That's a very important thing, and that's a

big role of pharmacies.

So opioids taken together with Benzodiazepines is a very dangerous drug interaction.

I told you earlier that the way that opioids kill is that they slow down breathing, they slow down heart rate, people fall asleep, their heart stops, they stop breathing and they don't wake up again.

When you add a sedative hypnotic like a Benzodiazepine, like a Xanax or Valium or Klonopin or Ativan to an opioid, you increase the risk of accidental death because those drugs together potentiate or make worse the problem of slowed breathing, slowed heart rate, falling asleep and not waking up again.

So this is a very significant drug-drug interaction.

Q. From a medical perspective, is there any reason that an addict or a nonaddict would want to take those two together?

Do they have any dopamine effect or are they mutually involved in something that's a high or something?

A. So in addition to the risk, increased risk of overdose with that combination, it's also a red flag because many people who become addicted to opioids will seek out and take Benzodiazepines at the same time to

augment the high or the euphoric feeling.

It is well-known based on medical literature and also based on patient experience that combining an opioid with a Benzodiazepine is a way to feed the addiction.

Q. All right. You go on to say then that in light of the materials summarized above, it's my opinion a red flag should have been in place no later than '07 or, no, no later than '07 based on medical literature, no later than '10 based on DEA enforcement actions.

The medical literature you're talking about is what?

A. There's medical literature going back quite awhile to the late 1990s, but I cite medical literature starting in 2002, showing that the combination of opioids and Benzodiazepines increases the risk of overdose death.

And that the combination is also commonly sought out by people who are misusing and addicted to those drugs.

Q. Okay. Thank you.

And then you continue to say, "Despite these red flags, the pharmacy defendants dispensed prescriptions for an opioid and a Benzodiazepine thousands of times in Lake and Trumbull Counties."

How do you know that to be true?

A. I know that based on data I saw showing the combinations of those pills.

Q. All right. Your next sub point is sub point 1, where you talk about pharmacy defendant Walmart lacked effective controls and actively undermined the efforts of pharmacists to prevent diversion.

Now, I've got to ask you these opinions based upon your understanding as a pharmacist, and I want you to limit yourself --

A. As a doctor, you mean?

Q. I'm sorry, as a doctor. I apologize. My brain just read pharmacist.

I need you to limit yourself to the efficacy and effects of these policies and procedures from a doctor's perspective.

Okay?

A. Okay.

Q. So within the framework of that, you start by saying, "By the year 2005, the prescription opioid epidemic was several years into its evolution, having begun in the mid-to-late 1990s."

Is that true?

A. Yes.

Q. Now, that brings up a really important question.

Some of these things we're talking about

are 10 years old, some of these things we're talking about are 20 years old, some 22, 23 years old.

Why does that matter today?

A. Well, it matters because, especially vis-à-vis the pharmacy defendants in this case, it is relevant to think about when they did what in terms of improving their screening procedures and setting up a system to prevent misuse and diversion, which is another part of their corresponding responsibility.

14:27:08 So appreciating the timeline, and in my opinion really noticing that although pharmacy defendants in this case made improvements over time, their efforts were too little, too late.

They had the means much earlier to put 14:27:29 better systems in place and they chose not to do it.

Q. I have mimicked your language that you use.

MR. BUSH: Objection, Your Honor.

THE COURT: I'll sustain the objection to that comment.

14:27:40 If you would ask a question, please.

BY MR. LANIER:

Q. Doctor, the -- specifically, did you examine the evolving efforts of the pharmacies on their red flags?

A. Yes.

14:28:03 Q. And by the same token, when you testified about a

paradigm shift and you explained that as a different -- I forgot your words. What were your words? Paradigm shift in the sense of what?

A. In terms of -- there was a paradigm shift or a big change in the way that the medical community was using opioids.

Q. Right.

So does the -- do the actions that go back decades affect that paradigm shift?

A. Yes.

I mean, that paradigm shift is really at the heart of what caused the current opioid epidemic. That paradigm shift in prescribing and dispensing led to the oversupply, which led to all kinds of different people having easy access to opioids, which led to people getting addicted and dying, which led to people turning then to heroin, illicit Fentanyl, as it became harder to get opioids, all of which are problems which we continue to deal with today.

Q. So you have looked, for example, at the November of 2005 Walmart section of its Pharmacy Operations Manual, which included instructions for handling suspected forged or altered prescriptions, such as contacting the prescribing physician, contacting the local authorities.

Did you find that to be from a doctor's

perspective an adequate manual for 2005?

A. No.

Q. Why?

A. Walmart did not give its pharmacists the tools that were necessary and that were available in order to detect typical --

14:30:04

MR. BUSH: Objection, Your Honor.

Direct to the *Daubert* ruling.

MR. LANIER: And for the record, Your Honor --

14:30:13

THE COURT: Yeah, I'll sustain that.

MR. BUSH: Ask for an instruction, Your Honor.

MR. LANIER: And for the record, Your Honor, I think it's in line with Page 13 of the *Daubert* ruling.

14:30:22

THE COURT: I think it was over the line.

MR. LANIER: Okay.

BY MR. LANIER:

Q. Ma'am, if -- Doctor, if enabled to, would you be able to walk through what was known in the medical community, what was known publicly, based upon news accounts, and correlate them to inadequacies in the Pharmacy Operations Manual of Walmart?

14:30:34

14:30:54

MR. MAJORAS: Same objection, Your Honor.

THE COURT: All right. Let's go on the headphones.

(Proceedings at side-bar:)

THE COURT: All right. Mr. Lanier, I will allow you to ask her -- I will allow you to ask her what was known in the literature as to what, what were best practices but I'm not going to allow you to talk about specific practices at specific pharmacies or stores.

That's beyond her expertise.

MR. LANIER: Okay.

Your Honor, I don't want you to think I was flagrantly disregarding.

THE COURT: You were right on the line.

MR. LANIER: What I was trying to do is on Page 13 of your *Daubert* ruling, you said, "Dr. Lembke is well qualified by experience to opine on the efficacy and effects of many of defendants' policies and procedures, such as defendants' alleged ignoring red flags for misuse and diversion, including concerns expressed by their own pharmacists."

So that's something you told me specifically in the *Daubert* ruling I could do, and I understand you're changing that now and that's fine, but I just didn't want you to think that I was just flying in the face of what you were doing.

MR. MAJORAS: Your Honor, two issues.

One, you're not changing anything in your ruling.

I'm asking you simply to enforce it.

14:32:40 Second, I'd also ask of the document that's been on the screen, there's a phrase in the document that specifically goes to the last part of that paragraph that says, "The pharmacists were precluded from doing a red flag examination," I'd ask that that be taken down from 14:32:57 the screen.

One other --

THE COURT: Well, I will allow her to -- I'll stick with Paragraph 13 as best as I can, so I think your question was a little over it and that portion 14:33:52 of the document was talking about incentives or lack of incentives, but I'll allow her to, as I said in Paragraph 13, she can opine that the pharmacists failed to provide -- she can opine as to what, what red flags were, and whether in her opinion that the pharmacists 14:34:20 were following those red flags or not.

MR. LANIER: Thank you, Your Honor.

MR. MAJORAS: Your Honor, Your Honor --

THE COURT: All right. Let's move on.

MR. MAJORAS: I'm not asking for 14:34:27 reconsideration. It's another matter, Your Honor.

(End of side-bar conference.)

BY MR. LANIER:

Q. So, Dr. Lembke, do you have an opinion -- thank you -- do you have an opinion on the efficacy and effects of Walmart's policies and procedures when it comes to ignoring red flags for misuse and diversion?

First, do you have an opinion?

A. Yes.

Q. And is that opinion based upon your work through the material that we've been talking about in your report?

A. Yes.

Q. And what is your opinion as to whether or not the policies and procedures of Walmart were effective for seeing and using properly red flags to prevent misuse and diversion?

A. Walmart's policies and procedures were not effective to detect red flags.

Q. Did it look to you, based upon your review of the literature and the media public accounts, that Walmart had a policy manual that was kept up-to-date with the state-of-the-art knowledge of how to detect and resolve red flags?

A. No.

Q. And did you work through the various sections of

Walmart's policy, Pharmacy Operations Manual, in deriving, in coming up with your opinion in this regard?

A. Yes.

Q. Did you have an opportunity to read -- I'll withdraw that, Your Honor.

14:36:52

MR. LANIER: Your Honor, may I ask a question? That's off my time, of the bench at side-bar?

THE COURT: Yes.

MR. LANIER: Please? Thank you.

14:37:17

(Proceedings at side-bar:)

THE COURT: All right. I just want to make sure everyone understands my ruling.

What I'm allowing her to do is answer the kinds of questions you just asked, her opinion as to whether policies were adequate or not.

14:37:28

I'm not going to allow her to opine as to why she thought -- what may have caused the inadequacies, what internal activities, reviews, policies, caused the inadequacies because that gets beyond her area of expertise.

14:37:52

MR. LANIER: Right. Right. That would go to state of mind and she can't testify about that, I understand.

THE COURT: She has no knowledge of internal policies, incentives, lack of incentives so I

14:38:02

will not let her to opine on that.

MR. LANIER: Understood.

THE COURT: What's your question, Mr. Lanier?

14:38:10 MR. LANIER: Well, I'll tell you, first, Your Honor, one thing I'm not doing and the reason I'm moving forward a little more rapidly is two of her bases for her opinions include a "Chicago Tribune" article and a "New York Times" article and you haven't had the chance 14:38:24 to hear the fuss over that. So I'm just going to skate through that, that's my own decision, and I'll put on the record I'm making that call right now. I can deal with you on that at another time with another witness.

But what I want to get into with her is the 14:38:38 memorandum of agreement that was put in place with the Government, because that does deal with accusations of Walmart's failure to comply with dispensing obligations, but I just know that those are touchy.

THE COURT: I think I've allowed -- I've 14:38:54 allowed that document in.

MR. LANIER: Thank you.

MR. MAJORAS: No. No, sir.

THE COURT: No?

MR. LANIER: I don't know that I used that 14:39:01 one yet, Your Honor.

THE COURT: Let me see it.

MR. LANIER: Okay.

MR. MAJORAS: Your Honor, for this, I'm going to turn it over to Ms. Fumerton, who is more familiar with this particular issue.

Thank you.

MS. FUMERTON: Your Honor.

THE COURT: Let me see the document.

MS. FUMERTON: And, Your Honor, I just want to note that this is one of the documents that was withdrawn this morning.

MR. LANIER: Judge, if that's the case, then I'll just move on because I don't want to misrepresent an agreement that we entered into.

I thought our agreement this morning was not to move them into evidence, but I can move on, Judge.

THE COURT: All right.

MR. LANIER: I'll have a chance to do this hopefully with a Walmart witness.

THE COURT: All right. I mean, if this is important to do it with this witness, I need to see the document. If it's better with another witness, a Walmart witness, that's fine.

MR. WEINBERGER: Your Honor, perhaps we could take our afternoon break. We can pull that

document out so you can look at it.

MR. LANIER: I think I can come back to it.

MR. WEINBERGER: Or we can come back to it.

THE COURT: Whatever. Let's move on, please.

14:40:09

MR. LANIER: All right. Thank you.

(End of side-bar conference.)

MR. LANIER: Thank you, Judge.

BY MR. LANIER:

14:40:15 Q. All right. Dr. Lembke, we may come back to that, but what I'd like to do right now is continue to look at the -- well, let's do this.

You have further opinions about failing to use or analyze dispensing data to assist pharmacies in

14:40:44 identifying red flags.

Suffice it to say if we took the time, we could walk through these opinions with you, right?

A. Yes.

Q. But for now, do you stand by that opinion as you've

14:40:59 got it before you and before the jury in this demonstrative?

A. Yes, I do.

Q. Your opinion continues to say, opinion six, that by increasing and assuring the supply of opioids and failing

14:41:17 to provide effective controls against diversion,

pharmacies contributed to opioid misuse, addiction, dependence, and death.

Do you believe that to be true?

A. Yes.

14:41:30 Q. And is it based upon reasonable probabilities, as you understand them within your science and medication background?

A. Yes.

Q. Opinion number seven, you have said, "No reliable

14:41:45 scientific evidence shows that long-term opioid therapy is effective for chronic noncancer pain."

Is that an opinion you hold?

A. Yes.

Q. Now, you've told us this in brief reference

14:42:06 earlier, but I'd like you to explain what you mean by, "No reliable scientific evidence," please.

A. Most of the studies looking at the benefits of opioids in the treatment of pain are studies lasting 12 weeks or less.

14:42:29 And if you'll remember, chronic pain is defined as pain lasting more than 12 weeks, the time beyond which normal tissue healing occurs.

So it is not appropriate or scientific to take a study that lasts 12 weeks or less and use that

14:42:52 study in support of opioids for longer than that time

period.

And yet, that is what was commonly done, beginning in the late 1990s for approximately a decade-and-a-half, that these short-term studies were used to support long-term use.

Q. All right. Let's move --

A. I mean, there are other aspects of those studies which make them unreliable, including the fact that many of those studies were funded by companies like Purdue, making the authors of those studies biased and the studies inherently at risk of bias.

Also, many of those studies were not appropriately constructed to detect for addiction, misuse or diversion, or included a sample population of hospitalized patients, which is not the same as patients who are walking around on the street.

So there are lots of different ways in which that science is not robust, and also is -- cannot be used for the treatment of chronic pain or long-term use.

Q. All right. The one study problem that you referenced that I think bears a little examination for a moment to see, if I'm understanding it right is, all right, chronic -- again, remind us -- means how long?

A. Pain that lasts more than 12 weeks.

Q. And you said the studies to show whether or not the opioids would help pain that lasts longer than 12 weeks, at least one of them of note, how long did it follow the patient?

14:44:46 A. Well, these studies, most of them, last less than 12 weeks and some of them much less than 12 weeks.

Q. How can someone do a study less than 12 weeks to determine if something works more than 12 weeks?

A. It's really not appropriate to do that, especially

14:45:12 given the risks of opioids that increase with longer term use.

Q. Did these study results make it into some of the materials that you've been talking about, for example, with CVS today?

14:45:32 A. So these materials, these misleading studies, were often used by key opinion leaders, paid for by Purdue, in these continuing medical education courses.

And the way the studies were presented is really confusing because oftentimes the patients would

14:45:58 have chronic pain conditions like chronic low back pain, so it was a population of patients who had chronic pain, and then they entered a study where they got opioids compared to a sugar pill for less than 12 weeks and the outcomes showed some modest benefit over a sugar pill

14:46:20 less than 12 weeks.

But that's not evidence for effectiveness long-term. It's short-term, it's evidence for short-term effectiveness in a population of patients with long-term pain.

14:46:35 But what would happen is then the opioid would be advertised as working in chronic low back pain patients, if you follow that.

They were promoted as working in chronic low back pain patients in a study that looked at chronic 14:46:58 low back pain patients but only assessed for short-term use.

Q. All right. Thank you for clarifying that for me.

Opinion number eight, you have said in opinion number eight that, "Certain manufacturers and 14:47:11 distributors misrepresented that the risk of addiction to prescription opioids is rare or less than one percent, when in fact prescription opioids are as addictive as heroin, and the risk of addiction is far higher than stated. The best conservative data show an opioid 14:47:31 addiction prevalence of 10 to 30 percent among chronic pain patients prescribed opioids."

Why is that an important opinion?

A. Well, that's important because it gets at the heart of this paradigm shift.

14:47:47 One of the main reasons that doctors felt

that they could prescribe opioids more liberally is because they were convinced by Purdue Pharma and others that as long as they were prescribing for a patient pain, their patient had a less than one percent chance of getting addicted.

14:48:10

So they thought, great, you know, I don't have to worry about addiction because I'm prescribing the opioid for pain, but if you really look at the evidence, what you see is that there's nothing to support that statement of less than one percent risk, which is a number that Purdue actually used in its educational materials.

14:48:26

And that, in fact, roughly one-in-four patients prescribed an opioid for chronic pain have developed addiction to opioids.

14:48:41

Q. All right.

Doctor, before we get into your opinion number nine, I need to ask you some general questions that will be relevant on opinion number nine.

14:48:57

You are familiar with the concept of the gateway effect.

You've used that phrase in your report, and you've used that phrase with me, correct?

A. Yes.

14:49:15

Q. And in some ways, you have explained the gateway

effect has been disproven, in some ways it's proven.

I need you to explain to us what is meant by the gateway effect as something that's been proven to be wrong, and then what is meant by the gateway effect where it's actually a legitimate expression.

14:49:34

All right? So first, what is not accurate on a gateway effect?

A. So the gateway effect is a theory that was developed decades ago to try to explain why it is that

14:49:55

people who use nicotine products, primarily cigarettes, and also alcohol, are more likely to go on to develop addiction to other substances colloquially referred to as hard drugs like methamphetamine, cocaine, heroin and other opioids.

14:50:16

And originally, the gateway effect was thought to be some kind of unique neurobiological phenomenon whereby something unique specifically about nicotine products or cigarettes would make a person progress to other drugs.

14:50:38

The way in which this original gateway effect has essentially been disputed or debated is that in all likelihood, there's nothing unique about nicotine that makes people progress to other drugs.

Instead, what's unique about nicotine is

14:51:03

that it's a legal drug. And as a legal drug, people have

ready access to it.

And as we talked about, the greater the supply and the easier the access to any drug, the more likely people are to try it and the more likely people are to get addicted to it.

14:51:17

And we know that addiction to any drug changes the brain and makes that person more susceptible to addiction to other drugs. That's called cross addiction. So once you become addicted to one drug, you are more likely to get addicted to another drug.

14:51:32

So in other words, this idea that there was something uniquely biological about nicotine versus any other drug that you might take is probably not true. That really what's moderating that effect is just that nicotine is legal and so it's easily accessible.

14:51:49

Q. All right. Have I written this accurately?

"Nicotine and alcohol does not lead to other drugs in a neurobiological phenomenon"?

A. I would say it does not uniquely. They do not uniquely lead.

14:52:03

So there is neurobiology, the pleasure-pain balance --

Q. Right?

A. -- the adaptation to gremlins but there is not something unique about nicotine.

14:52:14

Q. All right. So where does the gateway effect, where can we use that language more properly where it might be considered right in a sense?

A. The way that it's commonly used in our culture today is to talk about how one drug becomes a stepping stone to another drug.

So this drug was my gateway to these harder drugs or these other drugs, and so it's used commonly in that way that we start out with one drug, that changes our brain in the way that I've talked about, we develop the disease of addiction, and then we're more likely to progress on to other drugs or more potent versions of our original drug as we develop tolerance and neuroadaptation.

Q. In that regard, movement from one opioid to another, is that a legitimate scientific presence?

A. Yes. So that's essentially what has happened with the opioid epidemic.

What started out as a prescription opioid epidemic has now evolved into a heroin and illicit Fentanyl epidemic.

Q. All right.

So explain what you mean by what was initially a prescription drug epidemic has evolved?

A. So the increased supply of prescription drugs meant

that more people were exposed, more people got addicted.

As people progress in their disease of addiction, they need more and more to get the same effect, to counteract those gremlins, and/or they need more potent forms.

Also, people with addiction, just like everybody else, are price-sensitive so they will look at how much something costs in terms of their drug habit or how much effort it is to get that drug.

Opioid prescribing began to really escalate at the end of the 1990s with OxyContin promotion and continued to rise all the way until about 2012.

In 2011, the CDC said we are in the midst of a prescription drug epidemic, primarily opioids, and we need to do something about this. So it was in about 2012 or so that opioid prescribing and dispensing started to gradually decrease.

When that happened, you had more than a decade of people who had already become dependent or addicted to opioids who then, without treatment, needed to continue to get enough opioids, so many of those individuals turned to illicit sources, such as heroin.

Q. So when we talk about and documents and witnesses and studies talk about the problems of drug cartels bringing in Chinese Fentanyl or street heroin through

some illegal means, is there a relationship between that and the opioid epidemic?

A. The reason that the drug cartels infiltrated American communities around 2012, 2013, and started flooding those communities with heroin and then ultimately illicit Fentanyl --

MR. MAJORAS: Objection. Outside of expertise in terms of criminal enforcement issues.

THE COURT: Overruled.

14:56:13 A. -- was essentially that we had created a population of addicted individuals through the oversupply of prescription opioids.

So prescription opioids created the demand that heroin and then Fentanyl filled.

14:56:28 BY MR. LANIER:

Q. In that regard, in your report you offered opinion nine that, "Increased supply of prescription opioids contributed substantially to more individuals becoming addicted to opioids and transitioning from prescription

14:56:45 opioids to illicit sources of opioids, such as heroin and Fentanyl."

Is that correct?

A. Yes.

Q. You gave a chart in your report that you pulled

14:57:00 from *McCabe*, it looks like a journal of -- is that the

Journal of Addictive Medicine? Is that where you pulled this one from?

A. Yeah, the journal of -- the Journal of Addiction Medicine.

14:57:18 Q. Addiction Medicine, sorry.

Is that one where you've done peer review yourself or been affiliated with it in any way?

A. I think so, yes, I think I've reviewed for them before.

14:57:28 Q. And you've pulled this from an article entitled, "From Pills to Powder: A 17-year Transition From Prescription Opioids to Heroin Among U.S. Adolescents Followed Into Adulthood."

I want you to explain the picture, but, 14:57:45 first, can you tell us about the study?

A. Yeah, the study was an important study.

It followed teenagers prospectively, and what that means is that it looked at a population of teenagers and it followed them forward into time, which 14:58:03 is a powerful study design because you're not just looking backwards, you're actually following people forward.

And it looked at the patterns of prescription opioid use in that population relative to 14:58:19 whether or not those individuals went on to use heroin.

And what the study found was that both medical and nonmedical use of prescription opioids contributed to transitioning to heroin later in life.

So whether or not those teenagers got the opioid prescription from a doctor or they bought it from a friend or stole it from their grandparents' medicine cabinet, those individuals were all at increased risk of transitioning to heroin because of their exposure to prescription opioids.

14:59:02 Q. In that regard, is that -- well, explain. Did they follow medical use only, medical use followed by nonmedical use? Explain the chart now in light of that, please.

A. What this shows, what these data show, and there 14:59:24 are other studies showing the same thing as well, is that nonmedical use and medical use are often intertwined.

For example, a person, including teenagers, may get an opioid prescription for a wisdom tooth removal, and then they might not go back for a refill at 14:59:46 all, so they used it medically.

Or they might then start to use opioids nonmedically because they got a taste for it through their dentist prescription, and then they might use nonmedically recreationally and may or may not become 15:00:03 addicted but then at some later point, they may have

another injury and go back and be exposed to a medical prescription, interweaving like this in and out, again because the supply is so huge and it's everywhere.

Doctors prescribing more, medicine cabinets providing more.

Q. Okay.

A. So that's really the point here that nonmedical use contributes to the progression to heroin. Medical use contributes to the progression to heroin. It's all about increased supply, increased access, increased exposure being the most significant risk factor for the development of addiction.

Q. And does heroin work in the brain in the same way that the opioids themselves did in terms of your explanation of hijacking the brain and that dopamine-learning loop?

A. Yeah.

So opioids all work similarly in the brain's reward pathway.

Q. Okay. Next opinion.

THE COURT: Mr. Lanier, if you're going to move on to another opinion, it might be a good time to take a break.

MR. LANIER: Ready to break, Your Honor. Thank you.

THE COURT: Okay. Ladies and gentlemen, we'll take our afternoon break, 15 minutes.

Usual admonitions.

Thank you.

15:01:30 (Recess taken.)

THE COURT: All right. Please be seated for a minute.

I have to take up something before the jury comes out.

15:19:44 I had made clear that, at the request of the parties, that there was a sequestration of witnesses and so obviously one witness can't hear what another.

I've been advised that some experts have been listening, catching the livestream in the attorneys' 15:20:06 war rooms.

I don't think that's appropriate. No one had -- no one had requested permission, and they're going to be witnesses and they were supposed to be sequestered. And obviously, you know, if you're watching it in the war 15:20:20 room, it's the same.

And I had allowed, obviously, this livestreaming into the war rooms because that way you keep the number of attorneys down here, and that's fine. But witnesses weren't supposed to be seeing it.

15:20:33 So apparently these are Giant Eagle

experts.

I've just been notified of that.

MS. SULLIVAN: And, Your Honor, Diane Sullivan.

15:20:41 My apologies, Your Honor. In my experience, and I believe we can give you some case law, sequestered --

THE COURT: Ms. Sullivan, the point is no one -- no one said, "Well, all right, experts aren't

15:20:53 covered or are experts covered," so it was a blanket.

Now, so you should have raised that if you planned to have your experts, you know, watching proceedings.

MS. SULLIVAN: Our apologies, Your Honor.

15:21:07 Typically experts do either sit in and listen to other experts or review the transcripts to an opinion.

THE COURT: In some cases they do, in some they don't. All right. And that's done with discussion

15:21:19 and agreement; not sub rosa.

So it's a big problem. So I don't -- first of all, unless everyone agrees, that's got to stop immediately.

If everyone -- if everyone wants to exempt

15:21:32 experts, I mean obviously what works for one side, same

for the other.

So --

MR. WEINBERGER: We don't agree.

THE COURT: All right. Then it ceases.

15:21:39 All right?

MS. SULLIVAN: We'll make sure, Your Honor. Our apologies.

THE COURT: And it shouldn't -- it shouldn't have happened.

15:21:46 All right. So make sure, Ms. Sullivan, that they are out of that room like now.

MS. SULLIVAN: Will do, Your Honor.

(Jury in.)

THE COURT: Okay. You may be seated.

15:23:34 And, Ms. Lembke, I remind you you are still under oath and, Mr. Lanier, you may continue.

BY MR. LANIER:

Q. Okay. Your Honor.

May it please the Court, ladies and

15:23:44 gentlemen.

Dr. Lembke, we're in the homestretch. We're at opinion number ten and we are going to 14, so let's see if we can get this finished this afternoon.

Opinion number ten, "The increased supply

15:23:54 of prescription opioids contributed substantially to more

individuals, including newborns becoming dependent on opioids, increasing their risk for opioid-related morbidity and mortality, it's called the dependence effect.

15:24:13 Would you explain to us in general what you mean by that?

A. So this is one of the many harms caused by the oversupply of prescription opioids, and it is the physiologic phenomenon of dependence.

15:24:31 So dependence is related to addiction, but it's not the same thing.

Dependence refers to the very specific phenomenon of developing a physiologic adaptation to the drug such that it stops working at a given dose, which is

15:24:51 usually called tolerance, and that when the dose is decreased or stopped abruptly, people go into a classic opioid withdrawal phenomenon, which in some cases can be life-threatening.

So this is just making the point that

15:25:15 addiction is a harm of opioids, death is a harm of opioids, but dependence is also a harm of opioids.

We have now several generations of chronic pain patients who have been put on opioids by their doctors, developed a physical dependence, never really

15:25:35 developed the symptoms of addiction, and now are having

great difficulty getting off of those opioids or even going down to lower doses.

And it's a very labor-intensive endeavor to help them go down on those doses.

15:25:53 Q. Dr. Lembke, I suspect that several of our jurors are familiar with the DSM, I think is it up to number five or something now?

A. Yes.

Q. All right, the DSM, but for the sake of all of us and the record, would you explain what the DSM-V is?

15:26:10 A. The DSM is the Diagnostic and Statistical Manual of mental disorders. It's a very large book which mental health care professionals use to diagnose mental illnesses.

So if you open the DSM, and you go to a certain page, for example, the page that says Opioid Use Disorder, which is another way of saying opioid addiction, you'll see eleven criteria listed there.

And those criteria, if met, would qualify that person as having an Opioid Use Disorder or an opioid addiction.

The more of those criteria that are checked off, the more likely they are to meet criteria for addiction, but also it's a spectrum diagnosis, mild, moderate and severe. And depending upon how many items

they check off, they meet criteria, they meet mild, moderate or severe criteria for addiction.

Q. So when the jury hears about studies and statistics that talk about addiction, in general, at least in academia, would it be referencing those criteria from the DSM-V, those some range of 11 criteria?

A. So this gets confusing because when the DSM-IV edition -- the IV stands for the number of the edition -- when the DSM went from Edition Number IV to Edition Number V, it changed the language used to describe addiction.

In older versions, the DSM-IV and earlier, addiction was actually called abuse or dependence. So you could have opioid abuse or you could have opioid dependence.

In other words, the word dependence was the word that we used to use for opioid addiction.

Then with the new and more recent edition, the DSM-V, they got rid of the terms "abuse" and the terms "dependence," and they changed it to "use disorder."

So if nicotine was the problem, it was nicotine use disorder; opioids, Opioid Use Disorder; alcohol, alcohol use disorder, et cetera.

So --

Q. When you talk here, though, about dependence effect using the modern DSM, you mean something different than addiction, is that right?

A. Yes.

15:28:58 I mean the physiologic -- I mean it the way it's used in the DSM-V, the more current version.

"Dependence" in the DSM-V means the physiologic adaptation to the drug marked by tolerance and withdrawal.

15:29:17 That is often associated with addiction but not always associated with addiction.

So, for example, a newborn baby exposed to opioids in utero will go into opioid withdrawal when it is born, but that baby can't rightly be said to have

15:29:34 opioid addiction because that baby didn't engage in the behaviors that are really at the heart of addiction.

That baby was just exposed.

Likewise, a patient who received opioids from their doctor and always took it as prescribed can't

15:29:53 really be said to have an opioid addiction, but they can be extremely physically opioid-dependent.

And the attempt to try to taper them down may, in fact, unmask an addiction as they start to engage in drug-seeking behaviors.

15:30:09 But that's a distinction in the language

that we now use. And the dependence effect really is making the point that one of the many harms of the opioid, prescription opioid oversupply is dependence, babies being born dependent, chronic pain patients taking their medicines as prescribed but then getting dependent and having difficulty coming off.

Q. So if I put -- if I'm tracking with you right, I put under dependence, an example of an opioid baby or someone who is following doctor's orders.

Give us some examples that distinguish addiction. What are the hallmarks of addiction that make that language appropriate under the DSM-IV -- V?

A. Yeah.

So the hallmarks of the criteria for being diagnosed with an addiction can briefly be summarized as the four Cs: Control, compulsions, cravings, and consequences.

Control refers to out of control use of that substance, using more than intended, for example.

Compulsion refers to a lot of mental real estate occupied with thinking about getting the drug, using the drug, hiding drug use, and also a level of automaticity that's hard to control.

Cravings refers to that pleasure/pain balance tipping to the side of pain when people don't

have their drug and going into withdrawal, which is both physical and psychological, and can be experienced as so incredibly intense that patients will do whatever it takes to get their next fix. Again, usually not to feel euphoria or anything good, but just to get out of being in pain.

And then consequences is really the heart of addiction, especially continued use despite consequences. As addiction becomes more severe, people end up having all kinds of consequences, relationship consequences, job consequences, health consequences; and yet despite those consequences, continue to use their drug, again because of the very strong physiologic drive to restore homeostasis?

Q. In your report you mentioned that over the last 30 years, the liberal prescribing of opioids for chronic pain has created a legacy population of patients.

What do you mean by that?

A. So when we're considering the harms to our communities as a result of the opioid epidemic, we have to consider people who have become addicted, we have to consider people who have died, but we also, importantly, need to consider the very large numbers of patients who have become physically dependent and who are now suffering the harms of being on opioids and struggling to

get off of opioids, or at least go to a lower safer dose.

Q. Is it possible for us to be able to tell, just by looking at people as they walk through the grocery store, for example, if someone is dependent or an addict?

15:33:48 A. No. It's really impossible to tell.

Most people who take an opioid daily for three months or more will develop some degree of physical dependence and experience some degree of withdrawal when the dose is lowered and/or stopped abruptly.

15:34:07 But it's really not possible to tell who those people are unless you have their medication history.

And in terms of addiction, it's definitely very difficult to tell, also in part because people with

15:34:24 addiction become very adept at hiding their problematic drug use for, you know, obvious reasons. It's highly stigmatized, they're ashamed, they may need to hide their addiction in order to procure more of their drug.

So really impossible to note.

15:34:43 Q. Could a grandma getting lettuce and milk and pushing her cart to get Cheerios and Pop Tarts actually be addicted?

A. Yes. Absolutely.

And I wrote an article about that

15:34:58 phenomenon in 2016. I had a patient who roughly met that

description, who I was prescribing a Benzodiazapine to. Remember that's Xanax, Valium, Ativan, that category.

And I simply assumed, based on her appearance and her demographics, that she was not addicted to the Benzodiazepine that I was prescribing to her. And then I checked the Prescription Drug Monitoring Database and I discovered through checking that, that she had been doctor shopping and visiting multiple prescribers, getting the same or similar prescriptions that really was a revelation to me and made me realize how important it is to check the Prescription Drug Monitoring Database in order to know if that person may be in trouble because we really can't judge a book by its cover.

15:35:22 15:35:39 15:35:58

Q. All right.

In this regard, before we leave your opinion here on the dependence effect, what are the symptoms of withdrawal from dependence as opposed to addiction?

15:36:13

A. So the symptoms are really pretty much the same.

Different drugs have different classic withdrawal phenomena, and opioid withdrawal has very distinctive set of symptoms that are very similar to having the flu.

15:36:31

People have fever, they have chills, they

have muscle spasms, they feel achy all over so a lot of physical and muscle pain.

They may have muscle spasms which is where this term kicking the habit comes from. When people are in opioid withdrawal, their muscles will contract spontaneously and legs may kick out --

Q. Wait. That's where the expression "kicking the habit" comes from?

A. Yes. Yes.

Q. Okay.

A. They have pretty much fluid secreting from most orifices so they will have diarrhea, they will have vomiting, sometimes there will be a lot of perspiration, yawning, goose bumps is also a classic opioid withdrawal phenomenon, dilated pupils. And then, of course, the psychological symptoms from any addictive substance; anxiety, irritability, insomnia, depression and craving.

Q. Have you seen from your experience that withdrawal from dependence and addiction affects broader life beyond simply the person themselves?

In other words, does it have an effect on families and communities?

A. Yeah, I mean opioid, physical opioid dependence, whether in the context of an addiction or not, is very debilitating and the withdrawal phenomenon can be

incredibly painful.

It can, in fact, not only affect the person but of course, can affect entire families, sometimes so bad that patients need to be hospitalized for that -- for opioid withdrawal in order to stabilize their bodies during that process.

Q. All right. And in this regard, we will set aside opinion number ten and move now to opinion number 11.

Opinion number 11, you have said that, "An increased supply of prescription opioids contributed substantially to diversion of prescription opioids to individuals for whom they had not been prescribed."

You call this the tsunami effect.

Can you explain first what you mean, and then I'll ask you how you know this to be true or believe this to be true?

A. So what I mean by this is that the harms of the prescription opioid oversupply, which are at the cause of this opioid epidemic, have been incurred not just by individuals who have been prescribed opioids but also by individuals who never got a prescription because what the oversupply of prescription opioids led to was more access by all different types of people to prescription opioids, including teenagers, including other people stealing or diverting or selling.

So it just became very easy, especially in the first decade of the 2000s, to get prescription opioids, to buy them on the street, to get them from a friend or family member.

15:40:11 And so the harms, again, must be conceptualized, not just as the individual who received the prescription, but really all of us.

Q. You reference in your report a study by Cahn and others that was in the Journal of the American Medical

15:40:30 Association's Internal Medicine Journal in 2019, where you talk about it showing an opioid prescription to one family member increases the risk of overdose death to others in the family, even though they don't have a prescription.

15:40:47 Explain to us what you mean by that and why you include it in your report?

A. Yeah.

So this study looked specifically at families where an individual in the family had received

15:41:02 an opioid prescription from a doctor and compared that to families where there was no opioid prescription.

And what the study found was that in families where one identified family member was prescribed an opioid, that another person in the family

15:41:22 was more likely to die of an opioid overdose compared to

a family where there wasn't any opioid prescribing going on, which really gets to the heart of the tsunami effect that the harms are not just to that one individual but to anybody who comes in contact with that opioid supply.

15:41:46 Q. Then as we move from opinion number 11 to opinion number 12, you say the following: "The increased supply of prescription opioids through licit and illicit sources," first explain what you mean by licit and illicit sources?

15:42:10 A. So licit sources are prescription opioids that are used in accordance with the Controlled Substances Act; that is to say that are used for an approved medical indication in the context of a therapeutic relationship with a doctor.

15:42:32 Illicit sources are any time that prescription opioid goes outside of the closed boundaries of that opioid supply chain and is diverted to a person for whom it was not intended.

Illicit sources also includes 15:42:52 nonprescription opioids like heroin as well as opioids like Fentanyl, which is a prescription opioid but is also manufactured in illicit laboratories.

So there are licit forms of Fentanyl and there are illicit forms of Fentanyl.

15:43:11 Q. And you say the increased supply of prescription

opioids through licit and illicit sources resulted in a prescription opioid epidemic in the United States."

What do you mean by that?

A. Well, that means that prescription opioids obtained through legitimate channels, as those numbers went up, more people had access through prescriptions, more people got addicted, more people died, that's one important aspect of the epidemic, but also the prescription opioids that got diverted outside of that closed supply chain are another really important part of the opioid epidemic.

Q. Talk to us a little bit about the long-term effects of prenatal opioid exposure.

First, what do you mean by prenatal?

A. So prenatal refers to the time in a mother's womb before the baby is born.

Prenatal opioid exposure means that the baby is exposed to opioids in the mother's womb because the mother took opioids.

This opioid epidemic has been characterized by many more pregnant women getting prescription opioids for pregnancy-related pain, like round ligament pain, which is actually a normal part of pregnancy but which doctors started to treat with opioids, exposing those babies to opioids in utero.

Also, pregnant women who take illicit

opioids and thereby expose their babies in utero. And those babies are born sick. Basically they're born dependent on opioids, they go into opioid withdrawal, which is very painful. They need to be kept in the Neonatal Intensive Care Unit and often treated until their opioid withdrawal subsides and they can then be returned to the care of whoever is going to care for them.

And there are also studies showing that if you look at those opioid babies who are exposed in utero and you follow them prospectively through time into elementary school, that they continue to show cognitive and emotional delays that are significant and are not seen in babies who are not exposed to opioids.

So there's probably some long-lasting damage that occurs.

Q. As we continue to speak of the epidemic, is there science and studies that indicate an effect on the workforce within our communities from opioid -- from the increased supply of prescription opioids?

A. Yes.

So the work that has been done in this area has looked, for example, at Workers' Compensation, and compared workers who get injured on the job and leave work because of their injury and are treated with

opioids, are more likely to stay out of work longer and less likely to return to gainful employment than people who go out because of an injury and are not treated with opioids.

15:46:48 In other words, opioid prescribing in the context of a work-related injury has contributed to large numbers of workers not returning to the workforce, which can be understood as those individuals essentially being harmed by long-term opioid use, whether the harm is 15:47:09 because of dependence, whether they've developed addiction, whether they've died from the opioid, or whether they've just developed some of the other common side effect of long-term opioid use that we haven't actually discussed here yet today but which include 15:47:27 things like increased risk of depression, increased risk of cognitive problems, general decreased function because people are lethargic and sedated, actual worsened pain through a phenomenon called opioid-induced hyperalgesia, where as a result of taking opioids every day for long 15:47:49 periods of time, pain actually gets worse and people can experience pain in parts of the body that they never had pain in before because of the opioid.

Q. Are these side effects you're giving us a dependence, or addiction, or both?

15:48:07 A. They can be side effects of both.

They're just side effects of long-term opioid use.

Constipation, fatigue are some other ones.

Q. All right. I was trying to keep up with you.

15:48:20 You said increased depression.

A. Yes.

Q. Decreased cognitive --

A. Yeah, just decreased cognition, so patients can look a little bit demented when they're on opioids and

15:48:33 then you take them off and their head clears up.

Increased pain would be another one.

Increased fatigue. Constipation is another one. Hormonal imbalance. Men in particular on chronic opioid therapy will develop a markedly decreased

15:49:12 testosterone levels and in fact start to get a more female body habitus.

That's a pretty good list there.

Q. In addition to the science, the work you've done in this case, do you treat these people on a routine basis?

15:49:29 A. Yes. These are my patients.

Q. Now, you have talked about overdosing.

I would assume there are fatal and nonfatal overdosing.

Can you talk to us about the different

15:49:46 types of overdosing and the results of those?

A. Yes.

So nonfatal overdose -- and again, remember, that overdose is really a misnomer.

When I hear the word "Overdose," I think about somebody intentionally taking more than they were supposed to and dying as a result, when in fact the majority of overdoses on prescription opioids among chronic pain patients are happening at doses as prescribed.

15:50:23 And the reason for that is because as the brain develops tolerance to the pain relieving effects of the opioid, it then becomes necessary to go to ever-higher doses in order to get the pain relief back.

But the tolerance to the respiratory

15:50:44 suppression effects --

Q. The respiratory --

A. The slowed breathing effects.

Q. All right.

A. Doesn't happen at the same rate, it's slower.

15:50:54 So as the dose goes up, in order to recapture the pain relief, the breathing rate continues to be suppressed.

The brain doesn't adapt to that effect as quickly.

15:51:08 So it is very possible to try to go up on a

dose, especially if you've been taught that no dose is too high, then end up on a dose where your breathing is so slowed down that you essentially stop breathing and die from that.

15:51:25 But sometimes people don't die from that. Sometimes they're found and they're taken to the emergency room and they're revived, so that's a nonfatal overdose.

Sometimes somebody has Narcan available and 15:51:40 that's an opioid overdose reversal agent, so in the field they might revive them as opposed to the emergency room.

But again, all of these are forms of harm, and the numbers that we've looked at today really only captured overdose deaths, having captured the many 15:52:01 thousands of nonfatal overdoses that are part of the public nuisance or the ways in which our -- our communities have been harmed by the opioid oversupply.

Q. All right.

Doctor, if you would, please explain to us 15:52:16 what -- you said Narcan reverses the problem of the overdose?

What is Narcan?

A. So Narcan is an opioid receptor antagonist.

Remember, that the receptors are the 15:52:33 catchers mitt to which the molecules bind, and there are

opioid receptors in our brain and opioids bind those receptors and the result is both the short-term pain relieving effects as well as the effects on dopamine that we talked about.

15:52:49 What Narcan does is it comes into that receptor and it kicks off the opioid that's on the receptor and it binds in place of the opioid and essentially blocks the opioid from binding.

So for a person who is taking opioids, what 15:53:11 that will do is send them into immediate opioid withdrawal. It's not a comfortable or benign process. Once that opioid gets kicked off the opioid receptor, they go into opioid withdrawal, experiencing all the classic symptoms that we talked about.

15:53:25 Q. Okay. Did I write it correctly using your metaphor that it kind of fills up the catcher's mitt and kicks off the opioid?

A. Yes.

Q. Okay. And is Narcan one of these drug reaction 15:53:42 substances that is readily available to, like, EMTs and folks like that?

A. It's become more readily available. Some communities have it more readily available than others, but it's been one of the major harm-reduction 15:53:58 interventions in the opioid epidemic in an effort to save

lives and try to get people into treatment.

Q. All right. Let's leave the epidemic behind at this point, and let's move on to opinion number 13.

There is no doubt a cause and effect relationship exists between the oversupply of prescription opioids and the opioid epidemic.

Is that your opinion?

A. Yes.

Q. What is the basis for that opinion?

A. As opioid prescribing increased four fold between 1999 and 2012, opioid-related overdose deaths increased four-fold and opioid-related addiction increased four-fold.

And it is my opinion that it is the expansion of that supply that led to overdose deaths and addiction, that led overdose deaths and addiction to rise.

Q. But if people were to look at the recent studies, the recent studies seem to indicate that in the last few years, more of the deaths seemed to be coming from the illegal opioids; Fentanyl heroin, et cetera.

Why does that not change your opinion?

A. Because that is a logical end result of the gateway effect.

So the natural history of the disease of

addiction is that as people become more addicted, they need more and more to get the same effect, they look for cheaper, more potent quantities.

And essentially what happened, as opioid prescribing began to decrease, starting in about 2012, people who had already become addicted, and even people who were dependent and not addicted, had to look for cheaper, more readily available sources.

And they turned to heroin. And ultimately, Fentanyl entered the heroin market, which really increased the overdose death rate precisely because Fentanyl is so much more potent than heroin. Many people who thought that they were taking their regular dose of heroin were actually taking heroin laced with Fentanyl, which caused them to die because they had judged how much heroin they needed based on their standard supply, not knowing that there's Fentanyl in there.

And, remember, Fentanyl is really potent and really lethal because of its potency.

And today, we're really experiencing, you know, a Fentanyl epidemic where I have patients who are so addicted to opioids that they seek out Fentanyl. It's not even that they're accidentally taking it, although that still happens.

I would also add that Fentanyl has

infiltrated the counterfeit prescription opioid supply, so just last year, we lost a Stanford undergraduate who thought he was taking something like Percocet or Vicodin, but it was, in fact, a counterfeit Percocet or Vicodin that had been adulterated with Fentanyl.

And so he took it and he -- he didn't wake up again.

Q. Okay.

Doctor, opinion number 14, your last opinion to offer to the jury in this case right now is you have said that, "For the reasons explained, many parties bear responsibility for the misrepresentation of safety and efficacy, the ubiquitous distribution" -- well, let's stop.

Many parties. What do you mean by that?

A. The opioid epidemic wasn't just one person's fault or one group of persons' fault.

This was really something that we all need to take responsibility for from physicians to pharmacies to manufacturers to distributors.

Everybody had a role to play here and I think it's essential that we look back and honestly reflect on what our role was and try to do better.

Q. So when you speak of, "Many parties bear responsibility for the misrepresentation of safety and

efficacy, do you include in that Walmart?
A. Yes.
Q. Giant Eagle?
A. Yes.
15:59:17 Q. Walgreen's?
A. Yes.
Q. CVS?
A. Yes.
Q. The ubiquitous -- that's a Stanford word. What
15:59:30 does that mean?
A. Everywhere.
Q. All right. The everywhere distribution of
prescription opioids, and the unchecked dispensing of
prescription opioids, when you speak of that, do you
15:59:54 include the unchecked dispensing as you have uncovered in
your reviews of Walmart?
A. Yes.
Q. Giant Eagle?
A. Yes.
16:00:07 Q. Walgreen's?
A. Yes.
Q. CVS?
A. Yes.
Q. "To the extent other factors contributed, those
16:00:19 conditions were exploited to increase the extent of

harm."

What do you mean by that?

A. I mean that Purdue Pharma, for example, really exploited the good intentions of physicians putting aside pill-mill doctors, which exist and have always existed.

It was really well-intentioned doctors who, on a very large scale, began prescribing more opioids essentially because they were miseducated about safety and harms.

And so entities like Purdue Pharma understood what makes doctors tick and that they're very motivated to want to try to help people, and led them down the garden path of thinking that by prescribing more opioids, they would be helping people; and, in fact, shamed them into believing that if they didn't prescribe opioids, they were harming their patients by withholding that.

So that's an example of the ways in which those other entities essentially exploited cracks in the system.

Q. All right. Doctor, we've almost come to the end of the road.

And I want to thank you for that, but before I pass you, as the jury's already been informed, I believe, you are one of the experts from all parties who

is getting reimbursed for your time.

I want the jury to be real clear on that. You bill at $500 an hour?

A. Yes.

16:02:02 Q. And if you take all of the work that you've done in opioid litigation, not just in this case, but in all of the cases, about how much have you billed for your time at this point?

A. So I've been working on many different opioid

16:02:21 litigation cases for approximately the last four years, and it's taken up a good portion of most weeks during that time.

And I've made approximately $100,000 a year doing that work.

16:02:36 Q. And are you able to do that with Stanford's approval?

A. Yes.

MR. LANIER: And, Your Honor, with that, I'll pass the witness.

16:02:47 THE COURT: Okay. Thank you.

MR. BUSH: Your Honor, if you would give me a second.

THE COURT: Okay. Good.

MR. BUSH: May I proceed, Your Honor?

16:04:47 THE COURT: Yes, Mr. Bush.

CROSS-EXAMINATION OF ANNA LEMBKE

BY MR. BUSH:

Q. Good afternoon, ladies and gentlemen.

Good afternoon, Dr. Lembke.

16:04:55 A. Good afternoon.

Q. Nice to see you again.

A. I'm having a little trouble hearing you.

Q. How about that?

A. Better.

16:05:03 Q. Better? I'm not sure which one of these I'm going to end up using the most but I'll try, if you can't hear me, just let me know.

A. Okay.

Q. As you just did.

16:05:12 So you covered a lot of territory, and there's a few things that I do want to talk to you about, but let's start, first, with just setting the table a little bit.

You've talked -- you're obviously very

16:05:31 experienced in addiction issues, and this case is really about pharmacies.

So let me start there.

I think you did testify on direct that you're not a pharmacist, right?

16:05:48 A. That's correct.

Q. And you never went to pharmacy school?
A. That is correct.
Q. And you've never sat through a pharmacy licensing exam?
16:05:57 A. That is correct.
Q. And you've never worked behind the -- or at the bench in a pharmacy?
A. That is correct.
Q. And you've never worked for a pharmacy company like
16:06:11 one of the defendants in this case?
A. That is correct.
Q. So you would not hold yourself out, and maybe you've already said this, but you don't hold yourself out as a pharmacy expert.
16:06:39 You're testifying from the perspective of a doctor?
A. Well, I do hold myself out as an expert in terms of red flags and determining what are red flags, what to do about them, which are the same for a pharmacist and
16:06:57 physicians.
But it's true, I'm not a pharmacist.
Q. Right.
And you did -- you have testified previously that you don't hold yourself out as a pharmacy
16:07:06 expert?

A. I'm -- I'm not recalling that specific testimony.
Q. Well, let me ask you to take a look.
I think you have our documents up there, do you? Tab 1.
16:07:23 MR. LANIER: May I approach the witness and put the box by her that they left here?
MR. BUSH: I'm sorry, Mr. Lanier. I thought it was already there.
MR. LANIER: This is their box of 16:07:34 documents.
BY MR. BUSH:
Q. You recall giving testimony in this matter in Track One on April 24th, 2019? And you can see that on the front page of the transcript.
16:08:16 A. Yes, I have that document here.
Q. And when you gave that testimony, you were under oath and swore to tell the truth?
A. Yes.
Q. So take a look at, if you would, at Page 271.
16:08:30 And did you -- was this question asked and did you give this answer? At Line 10.
"And you wouldn't hold yourself out as having expertise with respect to pharmacy?
"Answer: That's correct."
16:08:52 Do you recall that?

Do you recall giving that testimony?

A. Yes, I see it now, and I recall giving it.

Q. All right. Thank you.

Now, prior to this case, and this is Track Three, the case involving Lake and Trumbull County and, I'm sorry if this is coming across, it sounds like it's coming across a little too loud but --

A. No.

Q. It's not?

A. No.

Q. Okay, fine.

Prior to giving your opinions in this case, you had not studied any policies or procedures the pharmacy companies had developed to guard against filling illegitimate opioid prescriptions?

A. That is true.

Q. Okay. And you hadn't written any academic papers that addressed that subject?

A. I did publish in 2016 an academic paper on red flags.

And checking the PDMP, which is pertinent to the case.

Q. Right. But that wasn't an article or an academic study on policies and procedures that related to pharmacies guarding against the filling of illegitimate

prescriptions?

A. It's true, that article didn't directly address pharmacies.

Q. And even to this date, at least as of your deposition in this case, you had not evaluated any policies and procedures of any other pharmacy company, other than the four defendants in this case?

And I guess Rite Aid was in this case at one point.

A. Yes.

Q. Five defendants, right?

A. That's correct. Yes.

Q. And so you're not in the position today to tell the jury how the policies and procedures that you have evaluated of the defendants in this case compare to policies and procedures that might be in place at other pharmacies across the country or in Lake and Trumbull County that are designed to guard against the filling of illegitimate prescriptions?

A. That is correct.

Q. And it's also correct that you haven't evaluated the -- withdrawn.

You have also not -- you specifically have not done anything to evaluate whether any of the smaller pharmacy companies or independent pharmacies have

policies and procedures to guard against the filling of illegitimate prescriptions?

A. That is correct.

Q. And you specifically have not done anything to evaluate whether they have any policies and procedures to use their dispensing data to guard against the filling of illegitimate prescriptions?

16:11:49

A. Yes. That is true.

Q. So let me talk a little bit with you about the Prescription Drug Monitoring Program.

16:12:32

You testified about that.

Doctors, I think you said this, that doctors have the ability to check the Prescription Drug Monitoring Programs in states where they're available?

16:12:53

A. Yes.

Q. And doctors, in the states where it's mandatory, are required to check?

A. Yes.

Q. So many of the things that a pharmacist would check for are things that a doctor would also check for?

16:13:06

A. Yes. Except that a pharmacist has potentially access to more information on a big data level than a physician would have.

Q. Well, you mentioned that a pharmacist would be able to see if a patient were doctor shopping.

16:13:25

Do you recall that testimony?
A. Yes.
Q. That's something that a doctor can see if he checks the PDMP, right?
16:13:32 A. Yes, but as I explained, there's that gap of time, such that a pharmacist would be able to pick up data that a physician would not.
Q. And I think the example you used was maybe six or seven -- a person went to six or seven different
16:13:52 prescribers, got six or seven prescriptions and then didn't fill them one at a time -- well, he had to fill them one at a time, but filled them all more or less at the same time, is that right?
A. Yes, that would be an example.
16:14:04 Q. Okay. You have no idea whether that ever happened in Lake and Trumbull County?
A. That certainly happens in my practice.
Q. Right.
A. And I don't think Lake and Trumbull County is -- is
16:14:15 unique in terms of the opioid epidemic and what occurred.
Q. But you don't actually know whether that has ever happened or the extent to which it's happened in Lake or Trumbull County?
A. I did not analyze data specific level, no.
16:14:31 Q. So if somebody had done what you suggested, went to

six or seven doctors, presumably he's going to, or she is going to need to do that again fairly shortly after the prescriptions are filled.

Do you agree?

16:14:47 A. Yes. It's very possible.

Q. And when they do that, the doctor's going to check the PDMP and he's going to see that the person went to six or seven different doctors the last time he or she got opioid prescriptions filled?

16:15:00 A. Yes.

Q. I think you testified -- well, I know you testified about the evolution of the opioid problem in this country.

A. Sir, I missed the word.

16:15:35 The what?

Q. The evolution of the opioid problem.

A. Evolution, yes.

Q. Evolution. Yeah, I'm sorry.

A. That's okay.

16:15:41 Q. I don't know why the --

A. My hearing is also not very good so that's a problem.

Q. I'm with you there.

Is that a little better if I put it down?

16:15:49 A. No.

Q. Here?
A. It was better up.
Q. That's better?
A. Yeah.
16:15:53 Q. All right. And I don't want to go back over all of the territory you went over in some of your testimony this morning where you described how people's thinking about opioids has changed over history actually going back hundreds or thousands of years, but focusing more
16:16:13 recently, as I understand it, in the 1990s and into the 2000s, that was when there was this paradigm change that you've talked about?
A. Yes.
Q. To encourage the use of opioids to treat pain to a
16:16:33 greater degree than had been before?
A. I'm sorry, I didn't catch the last part of your sentence.
Q. To encourage the use of opioids to treat pain to a greater degree than had been the case before?
16:16:45 A. Yes.
Q. And then that pendulum started to swing back sometime, what, near the end of the first decade of the 21st century?
A. Yes. Around 2012.
16:17:08 Q. 2012, okay.

And is that when you started to realize that the -- that, well, in -- is that when you started to have your opinion that opioids were being used too much and in inappropriate circumstances?

16:17:23 A. My opinion was not formed suddenly.

My opinion evolved over the first decade of this century, as I began seeing more patients who were addicted to and dependent on and dying from opioids they were getting from a medical doctor.

16:17:45 But I would say that in 2011, when the CDC announced that there was a prescription drug epidemic, and in 2013 when the California Prescription Drug Monitoring Database became available to physicians, those events certainly contributed to and solidified my

16:18:07 opinion.

And then, of course, I have done a lot of research since then, which has improved my understanding, not just of the role that opioid manufacturers played, but also the role of distributors and pharmacies,

16:18:24 something that I didn't appreciate initially.

Q. But it also improved your understanding of the risks and relative benefits of prescribing opioids in a variety of different circumstances.

Is that right?

16:18:38 A. I'm sorry, I'm not quite sure I understand the

question.

Q. Well, you focused on it improved your understanding about what various actors in the closed system of distribution were doing, but I'm asking whether it also improved your understanding of the medical uses, appropriate, in your view, medical uses of opioids?

A. Yes.

Q. Okay. And it would be fair to say that you were at the cutting edge of understanding those issues relative to other doctors around the country?

A. Yes.

Q. Okay. You -- sorry.

You testified a little bit about some programs that Purdue had in place, and you testified about some documents in particular that CVS or some documents you looked at that were part of your opinion or the basis for your opinion against CVS.

Do you recall that?

A. Yes.

Q. And you also testified about some of those similar programs with respect to certain of the other defendants in the case?

A. Yes.

Q. So let me ask you, at the time that you were -- at the time of the documents that you were looking at, which

was in 2001 -- is that your recollection?
A. I'm sorry, what was the first part of the sentence?
Q. At the time that those documents you relied on were written, it was in 2001, isn't that right?
16:20:09 A. Yes.
Q. Okay. Who at CVS, the company -- because I know that Mr. Lanier was getting you to make a distinction between the company and the pharmacists -- who at CVS knew that the paradigm shift in prescribing opioids
16:20:34 shouldn't have happened, wasn't medically appropriate?
Anybody you can identify?
A. Not in 2001.
Q. All right. Is that true for all of the other defendants?
16:20:46 There's nobody at any of the other companies that are defendants in this case who would have known that in 2001?
A. I'm not sure.
Q. You can't identify anybody?
16:20:54 A. Can I look at my report for a moment?
Q. If you think that will help you.
(Pause.)
A. That's correct, I can't identify anybody.
Q. Thank you.
16:21:28 And, in fact, things keep on changing to

this day.

You were talking about the DSM-V. That changed the definition of addiction?

A. Yes.

16:21:36 Q. And when was that?

A. I think the DSM-V came out in 2015, 2016.

I'm not remembering exactly.

Q. Okay. So as recently as 2016 --

A. Might have been -- might have been a little

16:21:49 earlier.

Q. Okay. Well, whenever it was, the definition of addiction itself changed?

A. Yes.

Q. Now, one of the opinions that you've given in the

16:22:27 case today is that the pharmacy defendants did not use their data to help identify problematic prescriptions, and put that however you want it if I haven't said it correctly.

A. I would say that pharmacy defendants didn't access

16:22:50 their data as early as they should have to try to help pharmacists identify red flags.

Q. Okay. Speaking of CVS for a moment, are you familiar with what RxConnect is?

A. Say that again.

16:23:04 Q. RxConnect?

A. I'm not hearing the second word. Rx?
Q. RxConnect?
A. RxConnect?
Q. Correct.
16:23:12 A. I'm not sure, no.
Q. Okay. So you didn't consider what system CVS had available through its RxConnect system and made available information for its pharmacists?
A. Well, I am -- I am familiar with CVS's prescriber
16:23:36 monitoring policy and prescriber validation policy from 2015 and 2014.

If that goes by another name, is that RxConnect?
Q. No, that's not. But we'll come back to that.
16:23:50 A. Okay.
Q. I plan to cover that, too.

So the answer to my question is you didn't evaluate RxConnect?
A. That's correct. Not that I'm aware of by that
16:23:59 name, no.
Q. And did you review CVS's prescriber suspension program in reaching your opinions?
A. I don't believe so.
Q. Okay. And did you review CVS's store monitoring
16:24:19 program in reaching your conclusions?

A. I -- if it's in my materials reviewed, then I reviewed it.

If it's not, then I didn't.

Q. And you don't recall anything about it, I guess, as you sit here today?

A. Well, I am recalling reviewing some documents about appropriate storage and monitoring that I do cite in my report, but I don't remember if it's called the document that you're referencing.

Q. Your answer makes me think this may be another thing where you didn't hear me properly correctly. Not your fault, but I said "store monitoring," not "storage monitoring."

I don't know what you heard.

A. So again, I'm not sure if I've reviewed that document. I'd be happy to look at it or if it's in my materials, consider that I did. So I'm not sure based on the way you're describing it.

I have reviewed a lot of drug utilization review documents from CVS, which do talk about how CVS intended its pharmacists to detect and intervene for various red flags.

Q. Right. But you don't recall reviewing -- well, you haven't looked -- let me put it to you this way.

Your opinion is not based on any review on

something called a store monitoring program at CVS?
A. If the store monitoring program at CVS is in my materials cited, then I did rely on it.
I'm not recalling the name of that
16:25:54 document. I reviewed over a thousand documents and my report is 400-plus pages long.
Q. I understand but you're here today giving your opinions orally in court and you have not relied for those opinions on the store monitoring program, is that
16:26:12 right?
A. Again, I do not know if I've reviewed that document.
I'm not currently recalling it. I may have reviewed it.
16:26:19 Q. Okay. Did you -- you didn't review the CVS forgery monitoring program in reaching your opinion?
A. I have reviewed documents regarding forged prescriptions for CVS.
I don't know if I've reviewed that specific
16:26:35 document by that name.
Q. Okay. You don't express any opinion that I recall in your report that the, excuse me, the CVS forgery monitoring program was inadequate or untimely.
A. I mean I do -- I do discuss forged prescriptions in
16:26:54 my report, vis-à-vis the *Holiday CVS* order, but I'm not

recalling a specific other instance where I talk about CVS and forged prescriptions.

Q. And you didn't mention that in your testimony today so far?

16:27:13 A. There are many things I did not mention in my testimony today so far --

Q. That's my point.

A. -- that are in my report.

And I did review and rely on in forming my

16:27:25 opinions.

Q. But it's not one that you testified about today, assuming you reviewed it at all?

A. I'm sorry, do you have --

THE COURT: Put on the headphones a minute,

16:27:40 please.

(Proceedings at side-bar:)

THE COURT: All right.

Mr. Bush, this witness, like anyone, simply answers the questions that they're asked. So to say you

16:28:00 didn't testify about this, you didn't testify about this, I mean, that's really not a fair question.

If she -- if her answer didn't include it, you can say did -- I mean something like that. But to just say you didn't testify about something is really not

16:28:18 a fair question and I don't think it's helpful to

anything.

MR. BUSH: All right. I'll try and ask it again.

THE COURT: Okay.

16:28:24 (End of side-bar conference.)

BY MR. BUSH:

Q. Can you hear me?

A. Yes.

Q. Okay. You did not review CVS's patient monitoring

16:28:56 program in reaching your opinions about CVS?

A. I reviewed many CVS documents.

I'm not now recalling one called the patient monitoring program, but these various monitoring programs go by many different and similar names.

16:29:19 If it's in my report as materials considered, then I did review it and I did rely on it in forming my opinions.

And I would be happy to look at it now if that would help.

16:29:39 Q. You did not criticize the CVS patient monitoring program in reaching your opinions in this case.

A. Again, I'm not even sure if I reviewed it.

We'd really have to look at my report and see if I reviewed it.

16:30:00 Q. All right. So let's go back to the Prescriber

Monitoring Program which you mentioned in your prior answer.

You did look at that?

A. You mean CVS's policies regarding Prescription Drug Monitoring Programs?

Q. No. Not the Prescription Drug Monitoring Program.

The Prescriber Monitoring Program. I think you said that you did look at that.

A. I said that if it was mentioned in my materials considered, then I did look at it, yes.

Again I've reviewed thousands of documents so it's hard for me to recall every document by name.

Q. I thought you said that you had reviewed it and that you thought it should have been implemented earlier.

A. Ah.

Q. Do you recall that testimony?

A. All right. So I know that by, as the Prescriber Monitoring Program in 2015, yes.

Q. Okay. And your understanding is that that program was not implemented at CVS until 2015?

A. That is my understanding, yes.

Q. How early do you think it should have been implemented?

A. I think it should have been implemented really from, the early 2000s, you know, as people started dying,

I would say by, somewhere between 2005 and 2010.

CVS should have used their own data to figure out where these pills were coming from and where they were going.

16:31:36 Q. And this was even before the pendulum started to swing back and people like you started to understand in 2012 that the guidelines for prescribing opioids were perhaps misguided in your view?

A. Yes.

16:31:50 And the reason for that is that pharmacies were in a position to see these problems much earlier, given their access to these very large data sets and granularity of detail regarding these prescriptions, not to mention that the DEA enforcement orders and

16:32:11 investigations were already happening by 2007, 2009.

The *East Main Street Pharmacy* ruling by the DEA came out in 2010, which made it very clear how pharmacies should be screening and intervening for red flags.

16:32:34 Q. Well, *East Main Street* didn't actually involve policies at all, did it?

A. I'm sorry, say that again.

Q. *East Main Street*, that decision did not involve policies at all, did it?

16:32:44 A. Well, the *East Main Street* case clearly identified

what was happening, that there was a very serious problem at the pharmacy level, and that pharmacies were not living up to their obligation, vis-à-vis the Controlled Substances Act to both create a system and implement that system.

Q. So actually *East Main Street* involved a particular pharmacy, not pharmacies in general all across the country, right?

A. Yes.

Q. Okay. And it didn't involve the policies of that particular pharmacy; it involved the actions of the particular pharmacist, right?

A. Yes, it did, but according to the Controlled Substances Act, as well as other sources, pharmacies have a responsibility to know about these DEA enforcements.

And the *East Main Street* case was published in 2010.

Q. You actually thought that the CVS Prescriber Monitoring Program was pretty good, right? Your only complaint was that it should have been earlier?

A. I thought it was pretty good as long as it was really implemented and not just on paper, but I thought it was too late.

Q. So you also expressed some opinions about the checking the PDMP, and I asked you before about whether

doctors have access to that.

But in Ohio in particular, I think you -- you understand that doctors had the obligation under certain defined criteria to check the PDMP before prescribing opioids to their patients as early as 2011?

A. Yes.

Q. Okay. And pharmacists did, too?

A. Yes.

Q. And the Stanford Clinic where you work and practice medicine did not have the obligation to check the PDMP in California until 2013, right?

A. That's right.

And even then, it wasn't mandatory in the State of California.

Q. Okay. And it wasn't mandatory in your clinic?

A. Starting in 2013 it was mandatory in my clinic.

Q. That's two years after it was mandatory and it was checked here in Ohio?

A. I'm sorry?

Q. Never mind. I withdraw the question.

So let me ask you about -- a question about the -- actually, withdrawn. Let me go back to a different topic here.

Dr. Lembke, you'll agree that even to this day, there are people, patients, who are prescribed

opioids to treat chronic long-term pain, right?
A. Yes.
Q. Okay. And that at least in some set of those circumstances, it's an appropriate treatment?
16:36:46 A. Yes.
Q. And you would also agree that for patients in that circumstance to have the pharmacist refuse to fill a prescription would be actually dangerous for them?
A. Yes.
16:37:09 Q. And I know that you've described a certain set of patients where if they're on chronic long-term pain, that they're likely to need more and more and higher and higher doses, but that's not true of everybody, right?
A. That's correct.
16:37:27 Q. Okay. And for some people, even though there's no study or a peer-reviewed or valid study in your opinion that supports the use of opioids to treat long-term pain, there are people who at least subjectively get a lot of relief from it?
16:37:48 A. In those individuals, what's not clear is whether they're getting actual pain relief from the chronic opioid therapy or whether they're getting relief because they're medicating withdrawal from the last dose.
I agree that subjectively they will endorse
16:38:06 release -- relief, but again it's not really clear that

the opioid is ultimately helping their pain condition, or their functionality.

Q. And the doctor who's prescribing the opioid medications in that situation is prescribing them for a legitimate medical purpose, right?

A. That is a complicated answer because we've created a legacy population of patients on chronic opioid therapy who are physically dependent, who now may not ever be able to get off of opioids, and it's not because the opioids are helping their pain condition, but because they've changed their brains irrevocably and can't not be on opioids.

So is that a legitimate medical condition? I mean, it's a humane approach to a problem that was created by the health care system.

Q. Well, if it's not a legitimate medical treatment, then the doctor shouldn't write the prescription, right?

That's your understanding of how corresponding responsibility and responsibility for prescribing works?

A. What I'm doing is drawing a distinction between what is treatment for chronic pain and what is a harm reduction strategy for someone who's become opioid dependent.

So it has become a legitimate medical

condition to continue opioids long-term in somebody who is so physically dependent that they just can't get off, but that wouldn't have been a legitimate medical condition prior to this opioid epidemic.

16:39:51 Q. Right. But if we're looking at what a pharmacist is doing right now, if they get a prescription for a patient like the one we're talking about, you would agree that they should fill a prescription?

A. Well, I would actually consider that if the patient

16:40:07 is on high doses, long-term, which is outside of the evidence, I would consider that a red flag that requires investigation.

I would -- I would say that the pharmacist would be required to communicate with the prescribing

16:40:24 physician and determine why they continue to prescribe high dose opioids, given all the risks.

And if the prescriber could explain that in this case the potential benefits outweigh the risks, either because the patient is getting pain relief or

16:40:48 because the risks of tapering that individual outweigh the risks of continuing on the medicine because of doctor-caused harm, then that would be okay to dispense.

But it would require investigation.

Q. So this person, if he's on -- or she is on

16:41:07 long-term opioid therapy, has been coming to the

pharmacist under this hypothetical for quite awhile, presumably you don't think that the pharmacist has to call the doctor every time she comes in?

A. No.

16:41:20 I mean, the red flags would be for very high doses at long duration or other harms related to drug-drug combinations, for example an opioid and a Benzodiazepine.

Again, we have a legacy generation where 16:41:39 three of individuals on a combination of a Benzo and opioid which never should have been started, which doesn't make it okay to just continue on, those need to be investigated.

Q. Okay. But if that person has been coming to the 16:41:51 pharmacy for let's say two or three years with the same doctor, getting the same prescription filled, that's not something that the pharmacist needs to call the doctor about every time the patient comes in.

Just a yes or no. You don't -- I realize 16:42:06 you may have other opinions about it, but they don't have to call the pharmacist -- I'm sorry -- the doctor, right?

A. Not every time, no.

Q. Okay. And if -- one of the things that the pharmacist, you would agree, would take into account is 16:42:22 her knowledge of the patient?

A. Yes.

But as I said before, our perception of the patient can be deceiving, which is why it's so important to check these objective data points.

16:42:35 Q. And one of the other things that the pharmacist would take into account is her knowledge of the practitioner who prescribed the opioids?

A. Yes.

Q. Okay.

16:43:17 MR. BUSH: I'm actually not a hundred percent sure what my team has here for Mr. Lanier's opinion slides.

Can you put that up?

Okay. Great. Perfect.

16:43:29 Can you put that up and go to opinion eight?

BY MR. BUSH:

Q. I'm moving. So if this doesn't work, let me know.

A. Okay.

16:43:42 Q. So I want to ask you about the last sentence here, "The best, conservative data show an opioid addiction prevalence of 10 to 30 percent among pain patients prescribed opioids."

Do you see that?

16:44:03 A. Yes.

Q. Okay. So that would mean between 90 and 70 percent of the patients do not have an addiction prevalence?
A. Yes.
Q. You've listed four misleading statements that you said the manufacturers had made, and I think around the early 90s, about opioids that led to the paradigm shift.
Do you recall that?
A. Could you say that again? I'm sorry, I had a hard --
Q. Yeah, you listed, by my count, four misleading statements that you said the manufacturers made in the early 90s that led to the paradigm shift in opioid prescribing?
A. Yes.
Q. Okay. One was that patients were unlikely to become addicted.
One was that no dose was too high.
One was that opioids were effective treatment for chronic pain.
And one -- the last one was that doctors could tell if a patient was likely to become addicted.
Did I get that more or less right?
A. Yes.
Q. Okay. And none of the pharmacy defendants in here made those statements in the early 90s?

A. Can I look in my report for a moment?
Q. Sure. If that will help you.
(Pause.)
A. So to my knowledge, none of the pharmacy defendants here themselves made those statements, but they partnered with Purdue who did make those statements.
Q. Well, the only thing that I've seen that you've referred to in your report and your testimony are the documents that you testified about in 2001.
Is there something other than that? Not the early 90s.
A. That's right, I'm talking about the late 1990s and beyond, right.
Q. So let's take a look at -- it's Tab 14. If you could pull that document out, please.
Actually while you're at it, Dr. Lembke, if you could pull out Tabs 12 and 13, that would also be helpful.
You let me know -- actually, we'll talk about 12 first so let me know when you have that.
A. Okay.
Q. And while Dr. Lembke's looking for that, that's P-08658.
Just let me know when you have it?
A. Yes, I have it.

Q. Okay. I think this was one of the documents you focused on as indicating that CVS participated in the -- what you call the false marketing of the manufacturers.

16:49:01 And I'd like to ask you to show me anywhere in this document where it refers to opioids, if you can find it.

A. I don't believe this document specifically refers to opioids.

16:49:37 It just refers to collaboration more generally.

Q. You would agree that educating your pharmacists about new medications, new drug products, is not a bad thing?

16:49:49 A. I'm sorry?

Q. You would agree that educating your pharmacists about new drug products is not a bad thing?

A. It would really depend on how the education was done and who did the educating.

16:49:59 Q. So if we get some new heart medicine or new blood pressure medicine, you think it would be a bad idea for CVS to have used this program to educate their pharmacists about what that new product is?

A. Yes. I think it would be a bad idea if that

16:50:17 education was funded by and done by the people who made

that heart medicine.

Q. Because the people who make the heart medicine are never going to tell you the truth about what it does?

A. No, it's not that they're never going to tell you the truth.

It's that they are certainly biased and motivated to sell their product.

Q. So this says that CVS, I believe -- let's look at this -- on Page 5, it says, "CVS NEWScript designed for new product launches, prepares pharmacists for first scripts to arrive," and then it says "Brief summary, one page, authored by CVS clinical department."

Do you see that?

A. Yes, I do see that.

Q. Okay. If CVS's, the clinical department writes the information about the new medication that's coming out, no reason to be worried it's biased, is there?

A. Well, again, it would depend on what CVS based their educational offering on.

If they based it on reliable evidence, that would be great. If they base it on material that they got from the drug manufacturer, that would not be good.

Q. And you have no idea what they based it on?

A. Well, I -- I do, in fact, know what they base it on because I've talked about examples of CVS basing their

education on opioids on materials that they, at least working and collaborating with Purdue around providing education.

Q. So let's stick with this as opposed to other things you may have testified about.

16:51:54

I'm asking with respect to the NEWScript, which is a document pursuant to this program which you said was facilitating the promotion of opioids.

You have no -- you've not even actually looked at a NEWScript that was produced by this program, have you?

16:52:11

A. I'm sorry, which document?

Q. You have not actually looked at a NEWScript? That's what this document is that CVS prepares and sends out to its pharmacists when there's a new medication.

16:52:20

You've never looked at one?

A. Again, I may have looked at one if it's in my materials considered. I'm not specifically recalling a document called NEWScript.

Q. And --

16:52:41

A. But I'd be happy to look at one now if you'd like me.

Q. Actually, your opinion is what your opinion is, Dr. Lembke. If you don't recall looking at a NEWScript that's where it stands right now.

16:52:52

But you also have not seen a NEWScript or any document that came out of this program that related to an opioid?

A. If it's not in my materials considered, then I didn't see it, and if it is, then I did.

Q. You have no recollection, as you sit here today, that you looked at any document related to an opioid that came out of this program that's reflected in P-8658?

A. Again, I have reviewed thousands of documents, and if I reviewed something that came out of this specific CVS NEWScript program, then it is in my materials considered.

Q. You can't tell us about any such document as you sit here today?

A. Not that I'm recalling, no.

Q. All right.

Okay. Let me ask you to take a look at what was behind Tab 14.

And just let me know when you have it.

A. Yes, I have it.

Q. Okay. And this is one of the documents you testified earlier -- about earlier today, is that right?

A. Yes.

Q. And this is the brochure that came from Purdue, it is a brochure that came from Purdue, right?

A. Sir, I couldn't hear the last part, but, yes, this is the brochure that came from Purdue.

Q. That's what I asked.

And it's titled "How to Stop Drug Diversion and Protect Your Pharmacy."

16:55:23

Right?

A. Yes, it is.

Q. Okay. And this looks like this was folded, maybe in thirds, like a brochure would be, so it's just to orient everybody on this.

16:55:40

So if you look at the second page, that's where the document text appears to begin and the first heading there is "Scrutinize Prescriptions."

Yes?

16:55:58

A. I'm sorry, say that again.

Q. First heading is "Scrutinize Prescriptions."

A. I'm really sorry. I'm just not catching the words.

Q. The first heading is "Scrutinize Prescriptions"?

A. I'm sorry, the -- I think my copy is stapled out of order.

16:56:36

Q. That's what I said before, I think this is actually a photocopy of a brochure so in real life, it would have been folded in thirds, I think.

And if you look on the second page, it looks like the first heading there is "Scrutinize

16:56:48

Prescriptions."

It's up on the screen.

A. Yes, I see that now on the second page.

Q. Yeah, okay.

16:56:55 And it has a number of things to look for:

"Does it look too good? Is the writing too legible? Is it a photocopy?" These are all things that the brochure is recommending that a pharmacist look at to determine whether this might be not a legitimate

16:57:15 prescription, right?

A. Yes.

Q. And I mean we can go through some of the rest of it with handwritten prescriptions, the ink from the preprinted information and the handwritten information

16:57:27 are generally slightly different colors, that's another thing that the brochure suggests should be examined to determine whether a prescription is legitimate?

A. Yes.

Q. And then it talks in heading two, "Types of

16:57:39 fraudulent prescriptions," and in heading three, "Patterns of possible diversion."

And then in heading three, it talks about, "Prescriber writes unexpectedly large quantities," right?

A. Yes.

16:57:54 Q. And that, "A diverter," meaning the patient as I

understand it, but correct me if you understand it differently, "returns too frequently, refilling the same prescription on a weekly or even daily basis," right?

A. Yes. That's what it says.

16:58:11 Q. And then back on the first page, but probably some different page in the real life of this document, it says, "Preventing diversion."

Do you see that?

A. Yes.

16:58:30 Q. Okay. There's nothing, as we've gone through this, that you see that's false about this brochure?

A. Nothing false, but as a complete policy, inadequate.

Q. I'm sorry. I didn't hear you this time.

16:58:50 A. Okay. There's nothing false about this, but as the entirety of a policy, it is inadequate.

Q. Well, so you're saying it could have talked about other things, but this is talking about drug diversion, right?

16:59:04 Not about other things.

A. Well, it's -- it's talking about what a pharmacist individually can do, but there's a whole context in which CVS Pharmacy could have allowed pharmacists to use their databases, for example, to issue blanket refusals to

16:59:26 known criminal doctors, which CVS Pharmacy did not allow

their pharmacists to do until later.

Q. Okay. So let's reset this and go back to where we are in time.

We're in 2001.

16:59:38 A. Um-hmm.

Q. And this is a document that you have testified is a basis, one of the bases for your opinion that CVS collaborated with opioid manufacturers, in this case Purdue, to falsely market drugs.

16:59:54 And so let's just stay on that.

There's nothing false about this document or -- leave it at that.

That's the question.

A. Oh, there's a question there?

17:00:13 Q. On the document, yes.

A. Okay. Okay.

Q. Sorry.

A. Again, there's nothing false about this document per se, but as I said, even in 2004, CVS was not allowing

17:00:28 pharmacists to have blanket refusals for known pill-mill doctors.

Q. I'm sorry, I can't hear you now.

A. Okay.

Q. Maybe you need to lean up a little closer to your

17:00:37 mic.

A. Yes.

Even in 2004, CVS was not allowing its pharmacists to deny dispensing pills for known pill-mill doctors.

17:00:53 So this document, in the context of not supporting pharmacists around preventing dispension for dispensing to pill-mill doctors, known pill-mill doctors, using their own data is really not a very useful document.

17:01:17 Q. You're not aware of any situation in Lake or Trumbull County where CVS prevented its pharmacists from refusing to fill a prescription that a patient presented from a pill-mill, are you?

Not even one?

17:01:38 A. I did not analyze at the level of CVS Pharmacies in Lake and Trumbull County, but I -- these are national policies, and they are applied to CVSes all over the country.

Q. You're not even aware of one situation in the

17:01:54 entire country, Dr. Lembke, in which CVS refused to allow its pharmacists to -- refused to fill or barred its pharmacists from refusing to fill an opioid prescription from a pill-mill doctor?

You don't cite it in your report, do you?

17:02:22 A. Well, I do cite the *Holiday CVS* case.

Q. That's not 2004, is it?
A. That is 2012.
I also mention the eleven million dollars civil penalty to do recordkeeping violations.
17:02:44 Q. Sorry, you're speaking down from your mic so I couldn't hear you.
Sorry.
A. Sorry, yeah.
I do cite specific instances where CVS
17:02:56 Pharmacies throughout the country at different regions in the country failed to fulfill their obligation according to the Controlled Substances Act.
Q. That's not really the question I asked.
I asked --
17:03:10 A. Okay.
Q. -- whether or not you're aware of any situation in which a pharmacist was prohibited from refusing to fill a prescription that was presented by a patient who got it from a pill-mill?
17:03:24 It's a very simple question. Are you aware of any situation like that?
You don't cite them in your report as far as I can tell.
A. I'm not aware of a specific situation where a
17:03:34 patient died as a result of getting their opioid from a

pill-mill doctor and filling it at CVS Pharmacy.
Q. You would agree with me that CVS never had any -- took out any TV ads promoting prescription opioids?
17:04:14 A. I'm sorry, I didn't catch the last part.
Q. Really sorry that we're having this technical issue.
A. It's a combination of my bad hearing and somehow not --
17:04:23 Q. Well, you're behind the screen, too. That's probably making it worse.
You're not -- CVS never had any TV ads promoting prescription opioids, did it?
A. CVS never had what?
17:04:34 Q. Any TV ads.
A. TV ads.
Q. Promoting prescription opioids.
A. Not that I know of.
Q. And none of the other pharmacy defendants had TV ads promoting prescription opioids, did they?
17:04:44 A. I don't believe so, no.
Q. And CVS never had any radio ads promoting opioids?
A. Well, CVS did partner with Partners Against Pain and they did have, I believe, radio ads.
17:05:03 Q. And you -- sorry.

A. But again, that was -- that wasn't CVS directly. It was their partnership with one of Purdue's front groups.

Q. And CVS partnered with Purdue at a time before you had figured out that opioid prescription standards were too lenient in the use of opioids?

A. Yes.

Q. And CVS did not take out newspaper ads promoting prescription opioids?

A. Not that I know of, no.

Q. And never had any billboards promoting opioids?

A. No.

Q. And none of the other pharmacy defendants did that?

A. Not that I know of.

Q. You -- none of -- none of the pharmacy defendants had any salespeople who went out to doctors like detailing them, like the manufacturers had, right?

A. That's correct.

Q. And that was one of the principal ways in which manufacturers in your opinion spread misleading or false information about the safety and effectiveness of opioids?

A. Yes.

Q. And, let's see, you also have, I think, rendered the opinion that the opioid manufacturers used key

opinion leaders to spread false information about the safety and effectiveness of opioids, right?

A. Yes.

Q. And neither CVS, nor any of the other pharmacy defendants, had any key opinion leaders that did that?

A. That's correct.

Q. You, in your report, which we've talked about some, you have an appendix? It's appendix, I think it's appendix one that lists for each of the manufacturers that you've given opinions about the false and misleading statements that they made to mislead the public about, and the medical community in your view, about the safety and effectiveness of opioids, right?

A. Yes.

Q. And that's about 30 pages?

A. Yes.

Q. And there's not any similar document for pharmacists; you don't list even one such statement in that appendix?

A. That's correct.

Q. Okay. Just give me one second, Dr. Lembke.

(Pause.)

You testified about the gateway effect. Remember that?

A. Yes.

Q. Okay. You've never used the term gateway effect in any peer review article that you published before you started working on the opioid litigation with the plaintiffs?

17:08:56 A. No, that's incorrect.

Q. Well, you recall testifying in New York at the *Frye* Hearing?

A. Yes.

Q. Let me ask you to look at Tab 24.

17:09:27 Let me know when you have that.

Do you have it?

A. Yes.

Q. And when you testified at the *Frye* Hearing, that was in court before Judge Gargiulo?

17:09:48 A. Yes.

Q. And you were sworn to tell the truth?

A. Yes.

Q. And you did tell the truth?

A. Yes, I did.

17:09:54 Q. And if you let me read to you from Page 156, Line 19 to 22.

"You never used that specific phrase, 'gateway effect,' or published that observation in any peer-reviewed journal articles, have you?

17:10:15 "Answer: No."

Do you recall giving that testimony?

A. It is true that I did not use that specific terminology in any of my publications, in peer-reviewed journal articles, but I did use the term "gateway" in my peer-reviewed book published in 2016, *Drug Dealer, MD*, which I wrote before I was involved in any litigation.

And I did address that concept proudly in my peer-reviewed journal article on checking the PDMP, which I published in 2016, where I do talk about how prescription medications, including Benzodiazepines, can lead people to turn to illicit sources.

Q. So let's take a look at your book.

It's -- I don't know if you -- I think we have the hard copy of the book but I can put the page up on the screen if that's a little easier because I'm just going to ask you about one page in there.

But if you want to look at the book, I think it's there behind Tab 8.

And can you put up Page 109?

A. So I'm not finding it here but --

MR. LANIER: May I approach and give her a copy, Your Honor?

MR. BUSH: I don't think that's the right -- I don't think that's the right thing.

THE COURT: I want to make sure that that's

the book that Mr. Bush wants her to see.

Well, Mr. Bush, Mr. Lanier has what looks to be her book.

MR. BUSH: Yeah, I was just trying to get it up on the screen, sir, so everybody can see it.

Oh, we have it. Okay. Somehow we have a little technical difficulty.

So do you have the page numbers there? Or is that just the cover? Just the cover? Okay.

17:12:35 BY MR. BUSH:

Q. So I'm going to try and use the Elmo and probably not going to be as good at it as Mr. Lanier.

Yeah, I'm not going to write on your book.

MR. LANIER: You're welcome to write

17:13:09 anything in it. I'm glad to help you on that.

BY MR. BUSH:

Q. So if you look at the first full paragraph on Page 109, and I want to direct your attention to the sentence that says, "However, the relationship between

17:13:22 doctors' prescribing patterns and the initiation of heroin use remains unclear."

That's what you said in 2016 when you published your book?

A. Yes, and I'm happy to explain what I meant by that.

17:13:33 Q. Well, what you said was that that pattern is

unclear to you in 2016; it's become clearer now?

A. No. What I meant by unclear was not whether or not people progressed from prescription opioids to heroin.

That was very clear.

17:13:49 What was unclear was what was causing that progression immediately. Was it the progression of the disease of addiction, or was it that doctors started prescribing fewer opioids?

And it really wasn't until a year or so

17:14:06 later, after the book had already been submitted, that studies came out to show that it was probably directly related to the contraction of opioid prescribing and people not being able to get opioids from their prescriber any longer.

17:14:24 Q. All right. Let's take a look at -- behind Tab 26.

A. Tab 26? Okay.

Q. And do you recall testifying at the trial in New York before the jury and Judge Gargiulo?

A. Yes.

17:14:58 Q. Let me ask you to turn to Page 85. That's where I'm going to ask you about.

And down at the bottom of the page, Mr. Hirschline asked you the question at Line 22, so 85, Line 22, "Before you were hired by the plaintiffs in this

17:15:19 case, you had concluded that the relationship between

opioid prescribing and the initiation of heroin use was unclear?

"Answer: Yes."

Do you recall giving that testimony?

17:15:30 A. Yes, I wrote in my book that it was unclear and I testified to that at trial. But again, what was unclear was what was directly contributing to people turning to opioids, to heroin, around 2013.

Was it that now we had a decade of

17:15:51 prescription opioids getting people addicted and that the progression of their disease meant they needed more and more to get the same effect and that's why they were turning to heroin, or was it specifically related to the fact that in 2012, opioid prescribing started to go down?

17:16:07 So that is the piece that is unclear.

Q. Okay. Thank you.

A. The actual gateway effect is not -- not unclear.

And, in fact, in my book, I have a subheading that says something like "Vicodin, the New

17:16:23 Gateway to Heroin."

Q. So Mr. Lanier, in his opening, which referred to a couple of different things -- sorry about that.

A. That was loud.

Q. That was loud.

17:16:41 A. That was very loud.

Q. Sorry?

THE COURT: Mr. Bush, excuse me. If you're about done, I don't want to cut you off, but if you're moving -- if you've got a ways to go and you're moving to a new area, I think it might be a good time for a break so you just let me know.

17:16:52

MR. BUSH: Yeah, it would be a good time for a break, Your Honor.

THE COURT: Okay. Fine.

17:16:59

MR. BUSH: So --

THE COURT: All right. Ladies and gentlemen, it's been a long day and afternoon. It's a good time to stop, so we'll stop for tonight.

Usual admonitions. Don't read, consider, view anything that you might see in the media. Don't discuss this case with anyone.

17:17:11

Have a good evening and we'll see you at 9:00 tomorrow morning.

(Jury out.)

17:17:55

THE COURT: Okay. Everyone can be seated.

All right. First, our -- I don't think the plaintiffs are offering any exhibits. I just to want take care of this.

Is that right, Mr. Lanier or Mr. Weinberger?

17:18:12

MR. LANIER: Your Honor, we are offering -- well --

MR. WEINBERGER: Your Honor, we're not offering any exhibits related to Dr. Lembke's testimony at this point.

17:18:20

THE COURT: Okay.

MR. WEINBERGER: We are -- we are seeking to move for admission certain other exhibits relevant to yesterday, and --

17:18:30

THE COURT: I'm confused because you didn't -- I admitted everything you offered yesterday.

MR. WEINBERGER: Right.

So --

THE COURT: Oh.

17:18:37

MR. WEINBERGER: -- I'd like to explain if I could, Your Honor.

THE COURT: All right. Briefly.

MR. WEINBERGER: May we have Dr. Lembke --

THE COURT: Oh, sorry, Dr. Lembke. You're excused.

17:18:47

You can stay if you want, but there's no reason for that.

I apologize.

All right.

17:18:57

MR. WEINBERGER: So what we've done is

we've kind of, following your suggestion, we have come up with some exhibits that we're going to move for admission that are partially related to yesterday's witness.

THE COURT: All right. I --

17:19:22 MR. WEINBERGER: Let me just explain to you what I did, if I may, Your Honor.

THE COURT: All right.

MR. WEINBERGER: So we've submitted those exhibits, a list of exhibits, to the defense and to

17:19:33 Special Master Cohen.

We haven't received back any objections to those exhibits. We don't have to deal with it right this very second.

THE COURT: Well, yeah, why don't you

17:19:44 discuss this?

I'll take these up at some other time. I mean, if there's no objection, I'll admit them.

If there's an objection, I'll have to figure out when and how I'll deal with it, and --

17:19:57 MR. WEINBERGER: So again, to --

THE COURT: There's none with Lembke, okay, that's what I'm asking.

MR. WEINBERGER: We're taking up your suggestion that we might be able to move this forward.

17:20:07 THE COURT: I'm going to raise that in

general.

Mr. Bush, are there any documents that you're offering at this time from your last cross-examination?

17:20:15 MR. BUSH: No, Your Honor.

THE COURT: Okay. I didn't think so.

All right.

MR. DELINSKY: Your Honor?

THE COURT: Yes.

17:20:23 MR. DELINSKY: I don't want to knock you off your agenda if you have --

THE COURT: Let's stay on my agenda, please.

All right. I want to figure out a better

17:20:31 way to deal with -- with documents and objections to documents.

All right. It clearly isn't working well and we're just starting. We've got to figure out another way.

17:20:45 It clearly is not going to work well to wait until 10:00 p.m., 11:00 p.m., 1:00 a.m., 2:00 a.m., whatever.

So that we're done with that.

So as far as I'm concerned, any objections

17:20:59 to authenticity have all been taken care of and there

weren't any or they weren't brought to my attention.

Now, admissibility is another thing, so I've got to figure out a better way to do it.

It's not -- it is not going to work waiting until the night before a witness' calling and then we get a whole raft of objections to exhibits.

So what are you all proposing? I'll listen to your proposals.

Either we have to forget about it and just I'll deal with them on the fly as they come in and they will be real fast, or you have to get, get them to me and Special Master Cohen at least two or three days before any objections, which means you'll have to give each other, you know, the documents two or three days before you're planning to use them.

The problem is there was no way to deal with these all in advance because everyone grossly overdesignated the number of witnesses you were calling and the number of documents you plan to use.

So --

MR. LANIER: I'm following Your Honor trying to figure it out in advance.

THE COURT: I understand.

MR. LANIER: I think frankly that if you'll deal with them on the fly, parties offer a document into

evidence at their own risk.

If it's not permissible evidence and we offer it or they do the same, then we're just sowing reversible error, which makes no sense for anybody. So I think by and large, lawyers may assert objections on the record to preserve an appeal, but --

17:22:38

THE COURT: All right. Well, as far as I'm concerned, any authenticity is over and done with so people can, you know, put the exhibits up and I'll decide, you know, you can probably ask a witness about almost any document if you -- do you know this, have you seen it, do you recognize it?

17:22:54

If they say no, I may not allow many questions unless there's a clear relevance or reason to keep going.

17:23:11

So I'll just, I guess that's the way I'll deal with it, just on the fly.

MS. FUMERTON: Your Honor, if I may make a suggestion.

17:23:18

I mean 48 hours would give us an opportunity to streamline this a bit. If that's not something you're inclined to do, I guess my request would be that the document not be published to the jury or sort of described before given to counsel so that we can raise an objection if it's something that we don't want the

17:23:31

jury to -- or we think it's impermissible for the jury to see.

Obviously once the, you know, plaintiffs describe the document to the witness and we think it's something that's completely out of bounds, you know, we can't unring that bell.

So if we're going to do it on the fly --

THE COURT: You can put it on the screen and say do you recognize it and then if there's an objection then, I'll deal with it.

Someone will have to hand me the document and I'll deal with it.

MR. DELINSKY: Your Honor, I thought that worked well with Mr. Davis yesterday.

Maybe your expectations are higher than mine. I thought that was relatively efficient.

MS. FUMERTON: See, I guess the one problem we have with that is publishing it to the jury. If it's handed to the witness, that's one thing, but I guess my point is that we would not -- would request it not be published to the jury until after counsel has had an opportunity to object.

MR. LANIER: Your Honor, historically what I've done in cases that I think would work quite well here, if I can throw out a suggestion is, before I offer

a document into evidence, I make sure that the other side has it, and before I show it or anything else, they've got it. If they're going to have an objection, so be it.

Historically what I've tried to do is go in
17:24:41 blocks of where we are, so given the block, here's a whole set of documents I'm going to use until the lunch break, go through these, take -- you know, I'll give them to them before Court, go through it, see which ones you have objection to.

17:24:58 THE COURT: I think that's fair.

Then if there's going to be an objection, then all you have to do is show it to the witness and then they can --

MR. LANIER: Exactly.

17:25:05 THE COURT: -- at that point, they can introduce an objection.

You can put it on the screen and say I'm going to ask you about this exhibit, and if at that point one of the defendants objects, I'll put on the
17:25:15 headphones. Someone will have to give it to me, and I'll quickly deal with it.

That just may be the way to do it.

SPECIAL MASTER COHEN: Could I ask a question?

17:25:24 It used to be the case, with changes in

technology, that at the podium, you could show a document to the witness only and then publish it after the witness said they recognize it.

THE COURT: Yeah, that's what we're doing.

17:25:36 SPECIAL MASTER COHEN: I don't know if you can still do that.

MR. LANIER: And I think as a practical matter, we can also make sure to hand the witness a hard copy --

17:25:43 THE COURT: Whatever.

MR. LANIER: -- and they've got it.

THE COURT: Just make sure the witness sees it and then if counsel objects, then they can object and I'll make sure someone hands it to me and I'll address it

17:25:52 at that point.

MS. FUMERTON: Your Honor, just to close the loop on this, I just want to make sure that we're still going to follow the procedure the parties agree to and that documents will be disclosed the night before.

17:26:03 MR. LANIER: Yes.

THE COURT: Yes, I'm not suspending that.

At least that's for your preparation.

MR. FIEBIG: Your Honor, can we raise one related point? This is Chantale Fiebig speaking for

17:26:17 Giant Eagle.

Today and yesterday as well, there were dozens of demonstratives created during the course of witness testimony that were not disclosed the night before, and we would ask that we be given copies of all demonstratives that have been shown to the witness and the jury, and that those be disclosed the night before as well.

THE COURT: Wait, wait, wait. The demonstratives created during the testimony, you mean Mr. Lanier's writings?

MS. FIEBIG: Yes, precisely, his writings and his drawings.

THE COURT: He can't disclose that to you before he writes it.

MS. FIEBIG: At a minimum, I think we should get copies and I think there should be a mechanism by which we can object.

THE COURT: First of all, those are not exhibits.

They will not be introduced. If he offers them, they're rejected so.

MR. LANIER: And I don't offer them.

It's no different than writing on a tablet or a chalkboard and drawing the scene of an accident.

And I am glad to give copies to you. We

will give digital copies. I've already done that with Ms. Swift.

THE COURT: If you want to give them so they can have them, that's fine.

17:27:13 MR. LANIER: Sure.

THE COURT: But they're not coming into evidence.

MR. LANIER: Right.

THE COURT: And there's no way to give them

17:27:18 in advance because he creates them on the fly.

But fair enough, Mr. Lanier, after a witness is done, if you can --

MR. LANIER: Absolutely.

THE COURT: -- assemble them and provide

17:27:27 them.

MS. FIEBIG: Yes, thank you. We'd like copies.

MR. LANIER: Yes. Absolutely.

MR. WEINBERGER: But again, Your Honor, to

17:27:31 try to facilitate what I think you're attempting to do here, we've started that process with a list of exhibits that we think should be admitted, whether they were testified to or not, and we submitted them to the defendants.

17:27:45 THE COURT: All right. That's fine.

MR. WEINBERGER: Yes.

THE COURT: And again, you know --

MS. FIEBIG: And, Your Honor --

THE COURT: If the parties can agree by stipulation that certain exhibits come in, that's fine.

17:27:52

MS. FIEBIG: Your Honor, could I --

THE COURT: Yeah.

MS. FIEBIG: I'm sorry.

Could I just ask for your guidance?

If in the event there is a drawing or some illustration that one of the defendants perceives to be either a mischaracterization of testimony or otherwise prejudicial, would you like that objection at the time --

17:28:00

THE COURT: No, you should object, Ms. Fiebig, contemporaneously. First of all, I'm going to be mindful of that and if I think that anyone is mischaracterizing the witness' testimony in what he or she is writing, I'm going to say something because I don't think that's proper.

17:28:14

It's got to be accurate or reasonably close; paraphrase, reasonably close.

17:28:30

If I think it's fundamentally inaccurate, I'm going to say something. And if I don't, obviously the other side should object and say that isn't what the witness said and I'll address it. That's a fair

17:28:47

objection.

MS. FIEBIG: Thank you, Your Honor.

THE COURT: All right.

So my rudimentary time keeping, I charged each side a quarter of an hour for our -- what we had to do in the morning, and then I had, in addition to that, for the plaintiffs with Dr. Lembke, 2 point -- 4.75 for a total of five, and Mr. Bush took one and a quarter so that's one-and-a-half for the defendants.

17:28:56 17:29:15 So, okay. We'll see everyone.

MR. DELINSKY: Your Honor, may I raise that one other issue I had?

THE COURT: Oh, sorry, Mr. Delinsky.

Fair enough. Yes.

17:29:24 MR. DELINSKY: Really quick, Your Honor.

I understand Your Honor intends to make exhibits public.

THE COURT: Well, that's -- anything that is admitted I think is public.

17:29:36 MR. DELINSKY: Your Honor, there is sensitive documents, not every document, not the vast majority of documents, if I could explain.

For instance, it didn't come in yesterday, another category did, personnel files. You know, pages 17:29:49 from personnel files, that's of a different ilk.

The second category, Your Honor, is yesterday documents were admitted pertaining to the operation of ongoing programs that reflect not only technology, it's nonpublic technologies, but also fashions in which a company like CVS reviews documents and it's not in the interest of CVS nor the public for that matter for the medical community to be seeing how the algorithms work, how they're graded out.

That's sensitive --

17:30:25 THE COURT: I wasn't aware any of that was admitted and I don't know what -- how we deal with that.

It's --

MR. DELINSKY: Well --

THE COURT: It's a public proceeding, all

17:30:33 right, so --

MR. DELINSKY: What I'd ask for, Your Honor, is when those documents arise, that there be an opportunity for redaction.

We just don't -- we just don't want pages

17:30:45 from personnel records.

THE COURT: Candidly, that should have happened well before.

I don't believe we had testimony on commercially sensitive --

17:30:54 MR. DELINSKY: We did, Your Honor.

Some of the documents --

THE COURT: If we had it, we had it, Mr. Delinsky.

You didn't say anything.

17:31:00 MR. DELINSKY: We had testimony, Your Honor --

There's a difference between the testimony --

THE COURT: I don't have time to take this

17:31:04 up now.

I raised this before as to how this would happen. Everyone knew this.

I, you know, document -- this is a public proceeding, all right? It's -- if you wanted to have

17:31:15 something redacted, candidly, it should have been redacted and not even -- not even dealt with and all we'd have is a redacted copy.

MR. DELINSKY: Your Honor, it could be the subject of testimony but we'll work with the other side.

17:31:28 THE COURT: If it's the subject of testimony, Mr. Delinsky, it is public. It's too late to do any redactions.

MR. DELINSKY: Your Honor, just so you know, the result of this will be to compromise programs

17:31:37 that are intended to stop diversion because it will be

made public, what the algorithms look for and how people can evade them, and I don't think that would be appropriate and I don't think it's what the Court wants but that's what I'm talking about.

17:31:48 THE COURT: Well, I don't recall anyone testifying about the details of algorithms.

MR. DELINSKY: Number one, there were, because there were certain scores that were asked about, you know, this, this is looking at a certain percentage

17:32:01 for this metric or that metric, and there was more information in the documents than was asked about in court.

And that's -- that is important information and I don't think anybody in this courtroom wants that to

17:32:13 be made public.

MR. LANIER: Your Honor, for the plaintiffs, I just told Mr. Delinsky --

THE COURT: Why don't you work with this? All right? Figure it out.

17:32:23 In the future, my preference would be that the redactions occur before they're even dealt with in court.

All right? So we don't have this anomaly of where I've got to make retroactive redactions, which

17:32:36 I'm not even sure is lawful, candidly.

Okay? So take care of it beforehand so that if you're doing it, we don't have this again.

If there's a particular document you want to hold off on, one or two now, I'll tell Mr. Pitts and we'll hold off for a day or two.

17:32:57

MR. DELINSKY: Thank you, Your Honor.

THE COURT: And try to work it out.

MR. WEINBERGER: Your Honor, for purposes of tomorrow's scheduling, can we have some indication as to how long the cross is going to take?

17:33:07

THE COURT: Oh, good -- all right.

Do you have a sense among the defendants how much longer you're planning to cross-examine Dr. Lembke? That's a reasonable request.

17:33:48

MR. BUSH: Two to two-and-a-half hours.

THE COURT: Peter, I think they said two to two-and-a-half hours collectively so that's about the morning, roughly about the morning.

MR. WEINBERGER: Okay.

17:34:02

THE COURT: Okay. Have a good evening.

(Proceedings concluded at 5:34 p.m.)

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C E R T I F I C A T E

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/Susan Trischan

/S/ Susan Trischan, Official Court Reporter
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